

**SCHOOL OF PUBLIC HEALTH
COLLEGE OF HEALTH SCIENCES
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**ECONOMIC BURDEN OF TYPE-2 DIABETES MELLITUS: A CASE STUDY OF
PATIENTS ATTENDING EASTERN REGIONAL HOSPITAL OUTPATIENT CLINIC**

BY

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THE AWARD OF MASTER IN PUBLIC HEALTH DEGREE**

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DECLARATION

I hereby declare that excluding precise references which have been duly acknowledged, this submission is my own work towards my Masters of Public Health dissertation and that, to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any other degree of the University or elsewhere.



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DEDICATION

This dissertation is dedicated to my mother, Beatrice Oborshie Torgbor for her prayers, encouragement and unflinching support given me throughout the course of my Masters of Public Health programme. I most of all dedicate it to my beloved son, Reginald Nikoi Kotei.



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ABSTRACT

Introduction

Diabetes Mellitus is fast attaining pandemic levels. Globally it exerts a huge toll on patients and society physically, financially and psychologically. The chronicity and complications associated with the disease leads to diverse financial and psychological burden especially to patients. This study sought to estimate the economic burden of type-2 diabetes illness.

Methods

This study was a cross sectional cost-of-illness (COI) survey which relied on quantitative data. Data were collected from May to June, 2016 among 282 diabetics who attended the Eastern Regional Hospital. Participants were interviewed using a structured questionnaire and supplementary secondary data were retrieved electronically from hospital records. Total direct cost was estimated by summing direct medical and non-medical cost incurred due to the diabetes illness. Indirect cost was estimated based on Human Capital Approach (or Income Approach). Patients' socioeconomic status was determined using principal components analysis. Data were entered into EpiInfo Version 7 and analysed using STATA Version 13 and Microsoft Excel Version 13. Sensitivity analyses were done to ascertain robustness of the cost estimates.

Results

Over 91% of study patients were suffering from diabetes complications. Type-2 diabetes was more prevalent among the elderly (mean age of 55 years). While the mean treatment cost of diabetics with complication was GHS175.61 (95% CI: 0-429.55) that of those without complication was GHS137.77 (95% CI: 53.93-221.61). The overall estimated total cost of diabetes treatment was GHS47,853.54 (US\$12,270.14). The mean and median total costs were

GHS184.45 (95% CI: 0-521.58) for complicated and GHS128.89 for non-complicated. The estimated direct cost constituted 92.8% of total treatment cost profile. About 44% of patients had their marriages affected by the diabetes conditions one way or the other. Type-2 diabetes affects self-esteem and self-confidence of patients with complications more than those without complications.

Conclusion

Analysis of estimated total treatment cost and related intangible burden of type-2 diabetes mellitus suggested that the economic burden the disease pose on individuals, businesses and larger economy is enormous. The complexity of the disease require constant and regular treatment regime to avoid complications and its associated cost burden.

Keywords: Diabetes Mellitus, indirect cost, direct cost, intangible cost, socioeconomic status, Ghana

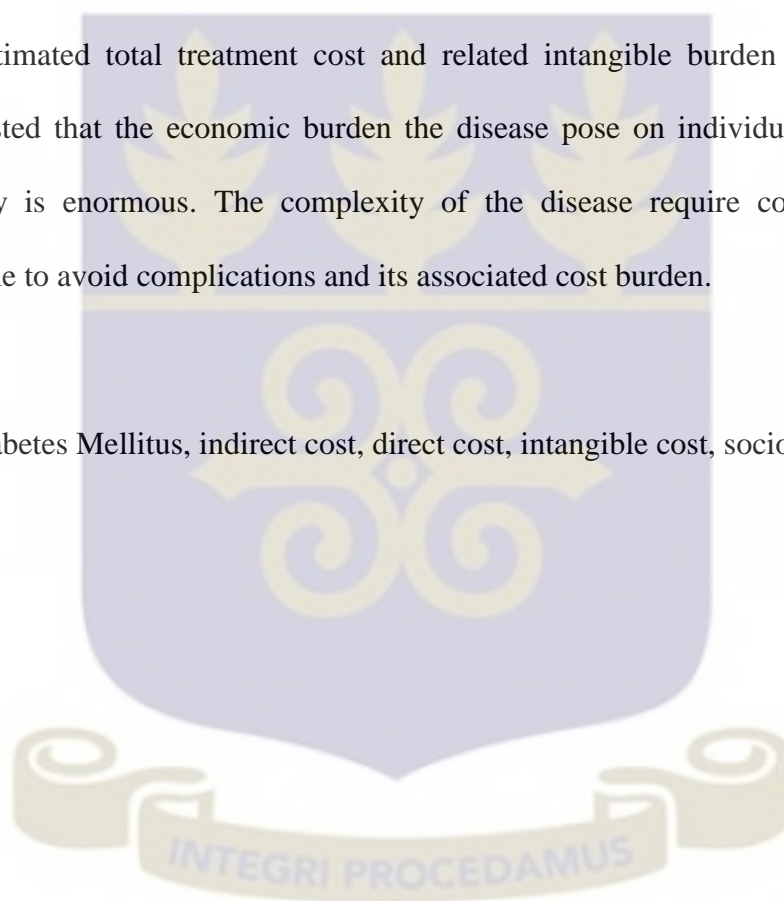


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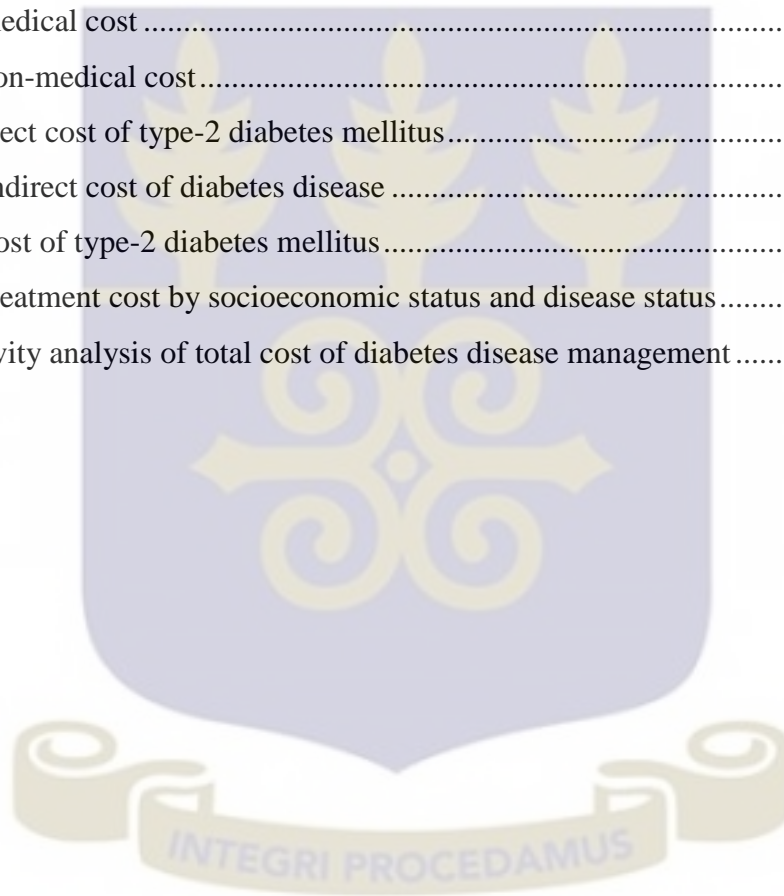
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LIST OF ABBREVIATIONS

| | |
|-------|--|
| CVD | : Cardiovascular disease |
| COI | : Cost-of-illness |
| EPI | : Expanded Programme on Immunization |
| EU | : European Union |
| ERHA | : Eastern Regional Health Administration |
| GHS | : Ghana Health Service |
| IDF | : International Diabetes Federation |
| LMICs | : low and middle-income countries |
| MOH | : Ministry of Health |
| NCD | : Non-communicable disease |
| NCDCP | : Non- communicable Disease Control Programme, Ghana |
| NHIS | : National Health Insurance Scheme |
| OOP | : Out-of-pocket payment |
| OPD | : Outpatient Department |
| PCA | : Principal Component Analysis |
| QALYs | : Quality-adjusted life year |
| RAPIA | : Rapid Assessment Protocol for Insulin Access |
| SA | : Sensitivity Analysis |
| SES | : Socio-economic Status |
| SSA | : Sub-Saharan Africa |
| UN | : United Nations |
| WHO | : World Health Organization |

CHAPTER ONE

INTRODUCTION

1.1 Background

Non-communicable diseases (NCDs) will become the leading cause of mortality worldwide by 2030 (Mathers & Loncar, 2006). The contribution of cardiovascular disease (CVD) to overall disease burden is determined by the risk factors associated with diabetes and hypertension. Progressive globalization and industrialization have brought about changes in the environment and lifestyle. This has led to more deskbound jobs and increased availability and high consumption of drinks and foods with high sugar, fat and salt content which results in rapid increase of diabetes (Kolb & Mandrup-Poulsen, 2010).

According to the International Diabetes Federation in 2009, four out of every five people with diabetes will soon live in developing countries. Type 2 diabetes is much more common and accounts for 90 to 95% of people with diabetes in sub-Saharan Africa (Hall *et al.*, 2011). It is a cardiovascular metabolic disorder with characteristics of chronic high blood glucose levels (fasting glucose level 6.1 mmol/L or 108 mg/dL and above) and a high risk of complications such as retinopathy (eyes damage), nephropathy (kidneys damage), and neuropathy (nervous system damage), hearing impairment, Alzheimer and CVD (Strine *et al.*, 2005).

The World Economic Forum (2009) reported that non-communicable disease burden as among the five most severe economic risk globally. Substantial economic losses in developing economies are as a result of reduced productivity caused by NCDs (Tunstall-Pedoe, 2006). To add to this burden of huge costs, diabetic patients and their families commonly go through

various forms of psychological and emotional stress due to the chronic nature and complications associated with the disease (International Diabetes Federation, 2009).

Abegunde *et al.* (2007) recommended that attention needs to be paid to the risk associated with chronic diseases including especially diabetes in low and middle-income countries (LMICs) due to the huge economic burden it possess. Diabetes was found to be among the top three non-communicable diseases OPD cases, rising to USD156,076 in 2010 from USD39,789 in 2005. Kumi-Ampofo (2015) reported that financial and non- financial household cost of diabetes mellitus in Ghana account for over two- thirds of household's income. Diabetes is also associated with some economic cost. These include direct costs which includes cost of treatment, indirect cost which comprises lost wages due to diabetes and its accompanying complications and intangible costs such as physical and psychological pains, stress, anxiety, reduced quality of life (Brown *et al.*, 2014; WHO, 2005). Notwithstanding the significant economic cost incurred by patients living with type-2 diabetes, there is limited study especially in Sub-Saharan Africa on the economic burden it possess to people living with the disease.

1.2 Problem Statement

According to Abegunde *et al.* (2007), the risk of chronic diseases including diabetes in LMICs need to be reduced, otherwise an estimated US\$84 billion of economic production will be lost between 2006 and 2015 in some 23 countries alone. In Ghana, diabetes was among the top three non-communicable diseases Out-patient Department (OPD) cases, increasing from 39,789 in 2005 to 156,076 in 2010 (NCD-CP-Ghana, 2010). Non-communicable diseases (NCD) and for that matter diabetes contrary to popular view, disproportionately affect the poor who are most

vulnerable to disease complications and mortality (GHS, 2014). Studies show that for every estimated 10% rise in mortality resulting from non-communicable disease, there is a decline in annual economic growth by 0.5% (Geneau *et al.*, 2010).

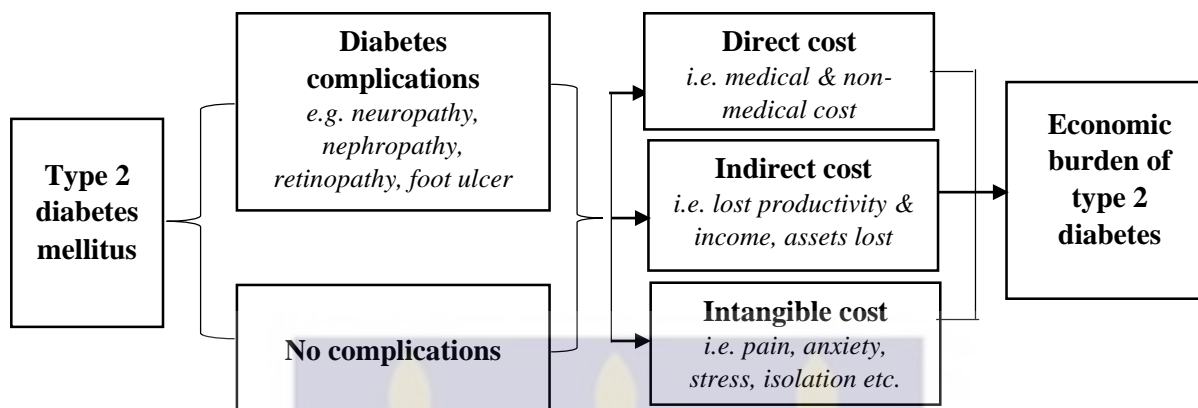
In Ghana, the National Non-communicable Disease Control Programme (NMCP) is advocating for funds obtained from taxes on tobacco and alcoholic beverages to be invested in NCD control (GHS, 2014). Due to lack of funding, they are also calling for integration of activities with other programmes like tuberculosis (TB) and Expanded Programme on Immunisation (EPI) so that funds from those programmes could be used for diabetics screening. A study conducted by Kumi-Ampofo (2015) in Ghana reported that financial and non- financial household cost of diabetes mellitus account for over two- thirds of household's income.

The costs associated with diabetes especially complications create a considerable economic burden for patients, families, and society (Gilmer *et al.*, 2005). The main driver of total cost is direct medical cost (Tagoe, 2012; Henriksson *et al.*, 2000; Kirigia *et al.*, 2009). This notwithstanding, adequate and robust studies on its economic impact are scarce, particularly in developing countries mainly because of unavailability of income data. In a preliminary interaction with the director of Non-communicable Disease Control Programme (NCDCP), the need for empirical evidence as basis for preventive and curative interventions in Ghana was accentuated. Hence, in order to aid stakeholders develop better and more effective strategies to ensure that diabetic patients live a longer and better life, there was need to understand the economic burden of diabetes and more importantly its complications and comorbidities. This study therefore sought to estimate the economic burden associated with management of type 2 diabetes and its complications/comorbidities among patients attending the Eastern Regional Hospital.

1.3 Conceptual framework

Figure 1 shows the theoretical relationship between type-2 diabetes mellitus and associated economic burden it poses to people living with the disease. The framework was based on the Cost of Illness (COI) concept. Many people living with the disease suffer certain comorbidities and complications (e.g. neuropathy, nephropathy, retinopathy, foot ulcer, skin conditions, hearing impairment etc.) which exerts a heavy economic burden on patients and households. Key among costs associated with treatment of diabetes complications are direct cost, indirect cost (i.e. lost productivity, income and assets) and intangible cost (i.e. pain, anxiety, stress, isolation etc.). The direct cost is made up of two components namely medical and non-medical cost. Medical cost includes expenditure on medical product and services like consultation, drugs, hospitalization and other treatment. Non-medical direct cost includes cost of visits to the health facilities (e.g. transportation), diet and other subsistence expenses. Patients living with diabetes especially those with complications also suffer indirect costs in the form of productivity losses due to patient disability, sick leave, time spent by family members accompanying patients when seeking care etc. Finally, individual suffering from diabetes complications bear the brunt of pains and suffering in the form of anxiety, stress, isolation, physical and psychological pains, all of which constitute intangible costs. Pain and suffering reduces quality of life of people suffering from the disease. The sum of all of these costs constitutes the economic burden of type 2 diabetes.

Figure 1: Conceptual Framework of economic burden of Type 2 Diabetes Mellitus



1.4 Justification

Diabetes patients in Sub-Saharan Africa have greater risk of serious complications and cost of treatment is high (Kirigia *et al.*, 2009; Mbanaya *et al.*, 2014). Furthermore, families with members who have complicated diabetes condition bear the brunt of higher out-of-pocket expenses which invariably reduces household earnings and lower quality of life (Dall *et al.*, 2010). In the Eastern Region of Ghana, diabetes mellitus is one of top five health condition. Some common complications include neural damage, foot ulcer leading to amputation, heart attack, kidney damage and blindness. Patients with diabetes also suffer from emotional distress, anxiety and physical and psychological pains. It is the number six cause of admission accounting for 2.4% of all admissions, and number nine cause of death accounting for 2.8% of all death in the region (GHS-ERHA, 2012).

Complicated diabetes is associated with great economic cost. These include direct costs (medical and non-medical cost of treatment), indirect cost which comprises lost wages due to the disease and intangible costs such as physical and psychological pains, stress, anxiety, reduced quality of life (Brown *et al.*, 2014). This notwithstanding, there is limited study especially in Sub-Saharan

Africa on the economic burden of diabetes, and Ghana is of no exception. This is mainly due to unavailability of data especially on income and productivity lost. Also, even though a reasonable number of studies have been done in developed countries on type 1 diabetes, studies on type-2 diabetes which is prevalent in developing countries are scarce. This study was therefore carried out to determine the economic impact of type-2 diabetes mellitus on patients attending the Eastern Regional Hospital. This would not only contribute to knowledge in the field but also educate and inform policymakers by providing fiscal information to support their decision-making processes.

1.5 Objectives

1.5.1 General objective

The general objective of this study was to determine the economic burden of type-2 diabetes mellitus of patient attending Outpatient Clinic at the Eastern Regional Hospital.

1.5.2 Specific objectives

The specific objectives were to:

1. Determine the proportion of type-2 diabetic complications.
2. Estimate the direct treatment cost of type-2 diabetes mellitus.
3. Estimate the indirect treatment cost of type-2 diabetes mellitus.
4. Determine intangible cost associated with type-2 diabetes mellitus.
5. Estimate the total treatment cost of type-2 diabetes mellitus by socioeconomic status.

CHAPTER TWO

LITERATURE REVIEW

This chapter reviews available literature on diabetes mellitus. The review aims to provide insight into the cost burden associated with management of the disease. It focused on: diabetes and its related comorbidities and complications; direct cost, indirect cost; and intangible cost associated with the disease as documented in scientific literature.

2.1 The Diabetes Disease

Diabetes mellitus (or diabetes) is a chronic, metabolic, lifelong disease that affects the body's ability to use the energy found in food. It occurs when the pancreas does not produce sufficient insulin, or when the body cannot effectively use the insulin it produces. Uncontrolled diabetes over time causes hyperglycaemia, or raised blood sugar which leads to serious damage to some parts of the body, example heart, blood vessels, eyes, kidneys, nerves etc. There are three major types of diabetes, namely type 1 diabetes, type 2 diabetes, and gestational diabetes (MedicineNet.com, 2015). Type 1 diabetes also known as insulin-dependent diabetes usually occurs in children and it is a chronic condition in which the pancreas produces little or no insulin by itself. Most people with the condition have the type 2 disease which is usually found in adults and occurs when the body becomes resistant to insulin or does not make enough insulin (MedicineNet.com, 2015).

The global prevalence of type 2 diabetes has risen substantially in the past three decades (American Diabetes Association, 2010). For people with type 2 diabetes, keeping blood glucose levels at normal (fasting glucose level below 6.1 mmol/L or 108 mg/dL) levels depends on

release and functioning of insulin from the pancreas living. However, the targeted cells of people with type 2 diabetes are not reactive to insulin effect thereby resulting in large amount of glucose circulation. Certain lifestyle factors like smoking, sedentariness, and high dietary fat intake promote the development of insulin resistance by the targeted cells. Insulin is commonly used medication for the treatment of type 2 diabetes. For people living with diabetes, access to affordable treatment, as well as insulin, is critical to their survival. Long standing evidence (Stolar, 2010; American Diabetes Association, 2010) show that early insulin treatment has a significant effect in delaying or preventing complications.

2.2. Common Diabetic Complications

Complications associated with diabetes can be divided into microvascular and macrovascular. Microvascular complications occur due to damage to the small blood vessels whiles that of macrovascular occur due to damage to larger blood vessels. Microvascular complications involves damage to eyes (retinopathy) leading to blindness; kidneys (nephropathy) leading to renal failure; nerves (neuropathy) leading to impotence; and severe diabetic foot disorders (foot ulcer) leading to amputation. Macrovascular complications include CVDs such as heart attacks, strokes and insufficiency in blood flow to legs. The severe microvascular and macrovascular complications due to diabetes mellitus has major implications for public health (Nisar *et al.*, 2015). Tunceli *et al.* (2005) reported that diabetics with both microvascular and macrovascular complications spend a total treatment cost of up to two-and-half times more compared to those without complications. The substantial cost of managing diabetes is aggravated by microvascular and macrovascular complications which are the major cause of healthcare costs (Beulens *et al.*, 2010; Deshpande *et al.*, 2008).

In sub-Saharan Africa, the risk of serious diabetes complications is high and costly (Hall *et al.*, 2011; Gill *et al.*, 2009; Morsanutto *et al.*, 2006). These include emotional distress (Aikins, 2005; Brown *et al.*, 2014), stroke (Kengne *et al.*, 2005; Tollman *et al.*, 2008; Walker *et al.*, 2010), neural damage, foot ulcer leading to amputation, heart attack, kidney damage and blindness (Elrayah *et al.*, 2005; American Diabetes Association, 2010), and also reduced life expectancy (WHO, 2005). Furthermore, apart from these complications, diabetes is often associated with certain comorbidities. For instance, patients with diabetic nephropathy have high-risk for excess cardiovascular morbidity (Papanas *et al.*, 2007; Ahmed *et al.* 2008). In Tanzania, 4.4% of type 2 diabetic patients presented with stroke upon diagnosis of diabetes (Walker *et al.*, 2010).

2.2.1 Diabetic retinopathy

This is caused by damage to the small blood vessel at the back layer of the eye, the retina, which leads to loss of vision progressively and eventually blindness. Diabetic retinopathy is a leading cause of blindness and visual disability. Symptoms usually include complaints of blurred vision. The onset and progression and threat of blindness due to diabetic retinopathy can be delayed by a good metabolic control (MedicineNet.com, 2015). In economically developed countries, diabetic retinopathy is the leading cause of new cases of blindness in adults. Furthermore, visual disabilities caused by certain types of glaucoma and cataract could be more common in diabetics than in those without the disease (Williams *et al.*, 2012).

2.2.2 Diabetic nephropathy

The diabetic kidney disease is caused by damage to small blood vessels in the kidneys. This may result in kidney failure, and eventually lead to death. Usually there are no early symptoms, but as

the disease progresses, patient may become anaemic, feel tired, not think clearly as well as develop dangerous electrolyte imbalances. Treatment include control of high blood glucose and high blood pressure, restriction of dietary protein and medication (MedicineNet.com, 2015). A study indicated that the costs of end stage kidney disease are considerable (Palmer *et al.*, 2008; Postma & de Zeeuw, 2009). Berger (2009) reported that the costs associated with end stage kidney disease were significantly higher in diabetes mellitus patients. A study conducted in Singapore showed that nephropathy significantly influence the total annual cost of diabetes treatment (Shuyu *et al.*, 2015).

2.2.3 Diabetic Neuropathy

This is damage to the nerve caused by diabetes disease due to damaged small blood vessels. This happens through direct damage by the hyperglycemia and decreased blood flow to nerves. This nerve damage can lead to decreased sensation, impotence and damage to limb. Common symptoms include numbness in extremities, impotence and pain in extremities. Sensory loss to feet can lead foot infections due to patients' inability to recognizing cuts (MedicineNet.com, 2015). If these conditions are not treated early, it can lead to amputation. These complications can be prevented or delayed if detected early and blood glucose brought under control. Diabetic neuropathy is a very most common and problematic complication of diabetes mellitus (MedicineNet.com, 2015). It leads to severe morbidity, mortality, and a huge economic burden (Nisar *et al.*, 2015). According to Boulten *et al.* (2005) and Driver *et al.* (2010), most significant contribution to diabetics' neuropathy morbidity is due to complications of the feet.

2.2.4 Diabetic Foot Disease

Diabetics' foot ulceration and often subsequent limb amputation occur as a result of changes in blood vessels and nerves. Thus, it occurs due to both vascular and neurological disease processes. It is one of the most costly complications of diabetes. Regular and proper care of the foot can prevent amputations (MedicineNet.com, 2015). There is significantly long-term disability and premature mortality associated with foot ulceration and infection (Abbas & Archibald, 2007; Mbenya *et al.*, 2014). Tanzania recorded mortality rate of over 50% among diabetic patients with severe foot ulcers who did not undergo surgery partly due to lack of money (Abbas & Archibald, 2007). Studies have shown that healing-resistant foot ulceration often leads to hospitalisation and amputation thereby making its treatment one of the most costly complications of diabetes (Washburn *et al.*, 2013; El-Alwady *et al.*, 2008).

2.2.5 Cardiovascular Disease

Hyperglycaemia (high blood glucose) damages the blood vessels through a process called “atherosclerosis”, or clogging of arteries. It narrows the arteries which lead to decreased blood flow to heart muscle thereby causing heart attack, or to brain leading to stroke, or to extremities thereby causing pain and decreasing healing of infections (MedicineNet.com, 2015). Symptoms include chest pain to leg pain, to confusion and paralysis. Though early detection and control of these complications can delay cardiovascular complications, controlling of other risk factors such as smoking, high blood pressure, high serum cholesterol and obesity is also very important (MedicineNet.com, 2015). Report from United States of America indicates that the direct medical cost associated with cardiovascular disease due to diabetes complications represents nearly 70% of total cost (Lee *et al.*, 2006).

2.3 Global Economic Burden of Type 2 Diabetes Mellitus

Diabetes is a growing challenge of both developed and developing countries and health care systems globally. Cost estimates from literature reviewed highlights the substantial burden that diabetes imposes on society. Diabetes substantially cause premature mortality and the situation is projected to worsen particularly in low and middle income countries as diabetes prevalence rise. Hence, there is urgent need to invest in prevention to mitigate the burden (Shaw *et al.*, 2010). Prevalence of type 2 diabetes is projected to increase by 69% in adults in low and middle income countries and 20% in developed countries between 2010 and 2030 (Roglic & Unwin, 2010). Whiting *et al.* (2011) further reported that majority of people with diabetes live in low and middle income countries, and by 2030 these countries will witness the highest increase.

The total estimated cost of diabetes in 2007 is including. Medical costs attributed to diabetes include \$27 billion for care to directly treat diabetes, \$58 billion to treat the portion of diabetes-related chronic complications that are attributed to diabetes, and \$31 billion in excess general medical costs

American Diabetes Association (2008) reported that the estimated cost of diagnosed diabetes was \$174 billion, which comprised of \$116 billion in excess medical expenditures and reduced national productivity of \$58 billion in 2007. Furthermore, annual medical costs per person on type 2 diabetes is US\$9,677 (Dall *et al.*, 2010). Furthermore, Dall *et al.* (2010) estimated productivity loss due to higher levels work absenteeism, disability, and early mortality because of diabetes to be US\$65 billion. Also, families with members who have complicated diabetes condition bear the burden of higher out-of-pocket expenses and reduced earnings as well as low quality of life.

In Sub-Saharan Africa, risk of diabetes complications is great and costly (Hall *et al.*, 2011; Ortegon *et al.*, 2012). These include emotional distress (Aikins, 2005; Brown *et al.*, 2014), stroke

(Kengne *et al.*, 2005), neural damage leading to amputation, heart attack, kidney damage and blindness (Nisar *et al.*, 2015), and also reduced life expectancy (WHO, 2005).

It is estimated that one-third of the world's population lacks consistent access to necessary medications partly due to the high price in the private market (WHO, 2005). In LMICs of SSA, diabetes management is a challenge because many people do not have access to a reliable, affordable supply of insulin. Despite initiatives from insulin-producing companies, including Novo Nordisk that have attempted to improve insulin supply by introducing price differentials, the price of insulin to the user is usually inflated along the distribution chain. A number of initiatives to improve the situation have been advanced by the International Insulin Foundation. This include a practical guide called Rapid Assessment Protocol for Insulin Access (RAPIA) that enables evaluation of access that diabetics have to both diabetes care and insulin (Beran *et al.*, 2005). The RAPIA have been piloted in Mozambique, Zambia, Mali and Nicaragua (Diabetes Leadership Forum - Africa, 2010).

2.4 Cost of illness

Though morbidity and mortality measurements are key for assessing the disease burden in populations, they provide partial analysis of the severe impact of illness on human welfare. Meanwhile the economic consequences of poor health can be enormous, hence the need for cost analysis and economic evaluation of diseases.

The cost of illness is the summation of all the costs associated with the treatment of the illness. These costs can be categorized into direct cost, indirect cost and intangible cost. There is substantial costs associated with treatment of diabetes mellitus and its consequent complications.

The substantial cost associated with the disease remains a major public health issue for countries worldwide due to the economic brunt it possess to diabetes patients in particular and society at large. As diabetes prevalence increases worldwide, the proportion of national health care budgets spent on the disease is ever-increasing (WHO, 2015).

2.5 Direct cost of diabetes disease

The direct costs of diabetes disease to individuals and their families include medical care, drugs, insulin and other supplies. In addition to these, in some countries, patients may also bear other personal costs, such as increased payments for health, life and automobile insurance (WHO, 2015). Also, there is direct costs to the healthcare sector which include hospital services, physician services, laboratory tests and the daily management of diabetes by use of products such as insulin, syringes, oral hypoglycaemic agents and blood-testing equipment (WHO, 2015). Direct cost of diabetes ranges from relatively low-cost items, such as primary-care consultations to very high-cost items, such as long hospitalization for treatment of complications (WHO, 2015). The direct cost of diabetic health care is estimated between 2.5% and 15% of yearly health care budgets depending on the local diabetes prevalence, complications and difficulty of treatment accessibility (WHO, 2013). Direct costs of diabetes disease management were generally found to be higher than indirect costs globally (Seurin & Suhrcke, 2015).

2.5.1 Direct cost to individuals

Sickness and poor health burdens the individual economically in the short term and, in the long term for chronic diseases like diabetes. A study by Kanavos *et al.* (2012) indicated that total direct cost burden of people with diabetes in five EU countries (i.e. France, Germany, Italy, Spain, and

the UK) was €90 billion. Per patient direct medical costs for Spain is estimated as €1,708 and that of Germany was estimated as €5,899 in 2010. Also, treatment of diabetes related complications accounted for significant portion of inpatient direct costs.

Diabetics especially those with complications in sub-Saharan Africa often face all kinds of difficulties (financial etc.) in undertaking regular access to treatment (Lamri *et al.*, 2014). De-Graft (2010) and Lamri *et al.*, (2014) reported that medical treatment is often expensive, irrationally prescribed and inconsistent. Hence, many people with diabetes often turn to traditional herbal healers whose treatment cost is less. Also more often than not, Ethnomedical and pharmaceutical treatments are combined, however many return to inconsistent medical care as and when they can afford (Lamri *et al.*, 2014).

The estimated direct cost of diabetes care per person is about 25% of the estimated annual income for the richest countries in sub-Saharan Africa, and almost 125% for the region's poorest countries (Kirigia *et al.*, 2009). Mbanya (2014) and his colleagues reported that the huge financial cost diabetes pose to society and individuals is predicted to increase in sub-Saharan Africa over the next 20 years due to rapid urbanization and the ageing population.

The estimated total economic cost (direct and indirect) of diabetes in the WHO's Africa region in 2000 was US\$67.03 billion or US\$8836 per person with diabetes per year (Kirigia *et al.*, 2009). Furthermore, Kirigia *et al.* (2009) estimated the direct cost of treating diabetes in 2000 to range from US\$2302 to US\$3207 per person. Anderson *et al.* (2011) found interventions to increase glycaemic control to be cost-effective. Also, by WHO standards for cost-effectiveness criteria, intensified treatment with insulin is cost-effective.

A study shows that up to 80% type 2 diabetes cases can be prevented, and even severe diabetes complications can be prevented or delayed for people with early stage diabetes (Hwang *et al.*,

2012). Hwang *et al.* (2012) further showed that preventive actions have been shown to be cost-effective for low- and middle-income countries. Hwang and his colleagues emphasised that it is cost-saving to improve glycaemic control in people with an HbA1c level of over 8%, however this often required intensified treatment coupled with lifestyle interventions.

Since the 1990s, the burden on people living with Non-communicable diseases (NCDs) has been worsened due to change in Ghana's health policy. Thus, in 1992, introduction of user-fees in all public health facilities resulted in a reduction in subsidies on all health services in the country as well as full cost pricing of drugs and pharmaceuticals (Jehu-Appiah *et al.*, 2010; Tagoe, 2012). Furthermore, the existing National Health Insurance Scheme (NHIS) does not cover all NCDs. Ironically, the introduction of the NHIS in Ghana reduced government's percentage budget expenditure on health by 39% in 2003 and increased household health care costs. Tagoe (2012) reported that average healthcare expenditure for households with respondent currently living with non-communicable diseases is 49% more than households with healthier respondents. This according to him places undue stress on households due to the relatively high direct cost of treating illness and the associated high indirect burden of illness. He further established significant difference in the mean household healthcare expenditure between household with a member having NCD(s) (GH¢13.09) and household with non- NCD(s) members (GH¢8.76) representing a 49% higher cost with a p-value (0.007). Another study done in Sweden reported that averagely, 60% of annual medical cost of type 2 diabetics in a study conducted in Sweden was attributable to diabetes (Henriksson *et al.*, 2000). Beran (2005) in a study conducted in Malawi found that one month of insulin treatment cost to a patient was almost 20 days' wages.

2.5.2 Direct cost on governments

Chronic non-communicable disease like diabetes severely impact on the economic development of nations (Mayer-Foulkes, 2011). Diabetes is a chronic and progressive disease which if not treated over time leads to complications that are costly to treat. Hence, avoiding complications through preventive policies and proper treatment saves money in the long term. However, many government especially in SSA find it difficult balancing treatment with prevention (Beran & Yudkin, 2006).

The cost of diabetes to national economies though hard to estimate can be very significant. Annual direct cost estimates recently quoted for Brazil was US\$ 3.9 billion), Argentina was US\$ 0.8 billion and Mexico was US\$ 2.0 billion and these costs were rising as diabetes prevalence increases. This implies that a rise in diabetes prevalence is associated with a concurrent increase in the direct health care cost from the disease (WHO, 2015). Generally, the diabetes share of direct health care costs range from 2.5% to 15% annual health care budgets, depending on local diabetes prevalence and the sophistication of the treatment available (WHO, 2015). Kanavos *et al.* (2012) reported that estimated direct annual cost was €5.45billion for Spain and €43.2billion for Germany in 2010. Likewise, Sweden's annual direct medical cost of drugs per patient averagely accounted for 27% of total direct cost of treating the disease (Henriksson *et al.*, 2000).

The UN Resolution 61/225 recognised “...*diabetes is a chronic, debilitating and costly disease associated with severe complications, which poses severe risks for families, [UN] Member States and the entire world and serious challenges to the achievement of internationally agreed development goals including the Millennium Development Goals...*”. In 2006 African Diabetes Declaration called on all stakeholders and partners in diabetes, and particularly governments of

African countries to prevent diabetes and its related chronic complications, and to improve quality of life and reduce morbidity and premature mortality from diabetes.

Beran *et al.* (2008) reported that medication, insulin and equipment like syringes needed for diabetic management are commonly in short supply in many countries. Furthermore, in countries where they are available, often they are unaffordable due to limited access to subsidised medicine or unavailability of subsidy. Substantial difference exist in the availability and price of insulin obtained through the private and public sectors due to a combination of taxes, mark-ups etc. Due to these reasons, since 2001, a differential insulin price are offered by Novo Nordisk to the world's less developed countries, of which 33 are in sub-Saharan Africa (UN Least developed countries). Novo Nordisk's differential pricing for insulin supplied is targeted basically at the UN least developed countries where insulin is sold at a maximum 20% of the average price for Europe, USA, Canada and Japan. Annually, insulin is offered at a differential price to all 49 governments of the Least Developed Countries defined by the UN84.

2.6 Indirect Cost of Diabetes Disease

Majority of diabetics with complications may not be able to continue working or work effectively as they used to prior to the onset of their condition. Severe complications, absenteeism, disability, premature retirement or premature mortality could cause productivity loss (WHO. 2015). Though the estimation of cost to society in relation to productivity loss could be complex, in many cases where estimates have been made, the costs may be as great or even greater than direct health care costs. Also, families suffer loss of earnings as a result of diabetes and its complications (WHO. 2015). Health conditions curtails people ability to engage in economic activity. Schofield (2014) reported that when this happens, individuals

bear the cost of lost income in addition to the burden of the diabetes disease, the impacts of lost productivity and income taxation revenue is endured by Government. These national costs are in addition to the Government's direct healthcare costs.

Brown and his colleagues (2014) showed that 15% of family members of diabetics had to stop work to care for a family member with diabetes, and 20% had to cut back on work.. Also, since in SSA, family members often endure the primary responsibility for care, the effect on the family exceeds monetary costs. Patients and affected family members are hugely burdened in instances where home-based care is required. Apart from the fact that people with diabetes have to pay for medication, consultation, treatment and transport to treatment centres, they also suffer from loss of earnings due to days off work thereby risking losing their job. Thus, in addition to the direct cost associated with diabetes and complications, the disease affect not only patients but their families and to an extent even the community.

Beran (2005) in a study conducted in Malawi found that affected families often suffer economic loss through giving up work to provide nursing care for family members suffering diabetes illness causes (Diabetes Leadership Forum - Africa, 2010). A study conducted in Ghana by Tagoe (2012) showed that households with respondents currently living with non-communicable diseases and hence were not working was about 59% more than households with healthier respondents. Eleven percent of the respondents attributed their unemployment status to their health. Due to limited support networks for people living with NCDs in Ghana, especially in rural areas (Aikins, 2005), patients had to depend on household members, friends and social groups to support treatment and management of disease condition (Tagoe, 2012).

Studies showed that beyond the direct effect chronic illness like diabetes has on individual workers, it also reduce the profitability of business due to higher employee turnover, absenteeism and loss of skilled workers (Bolin *et al.*, 2009; America Diabetes Association., 2008). Thus, the illness causes productivity loss to employers and the national economies due to lost work hours, sub-optimal performance through physical and psychological problems, early retirement, reduced life expectancy and death. This leads to dwindling of business activities and investment in infrastructure thereby stagnating or reducing economic growth (America Diabetes Association, 2013). Schofield (2014) showed that the median annual income of people who go on early retirement in Australia because of their diabetes condition was significantly lower compared to those without a chronic health condition and employed full time who received almost five times more income. Additionally, the labour force shrunk by 11,300 people aged 45–64 years due workers’ diabetes condition. Diabetes through its impact on labour force participation at the national level caused individuals with diabetes to lose about AU\$384 million in earnings, government welfare payments of AU\$4 million, taxation revenue loss of AU\$56 million, and loss of AU\$1,324 million in 2010 GDP (Schofield *et al.*, 2014).

2.7 Intangible Cost of Diabetes Disease

There is a higher risk of mood and anxiety disorders among individuals with diabetes relative to those without the disease. These risk which affect quality of life are termed as intangible cost. Pain, anxiety, discrimination at workplace, difficult in obtaining jobs shortened professional due to complications, stigmatization and other factors which decrease quality of life (WHO, 2015). Prevalence of depression among diabetics vary by lower and higher

income countries, although there is disproportionate evidence base for the income countries (Egede & Ellis, 2010).

High risk of complications such as retinopathy (eyes damage), nephropathy (kidneys damage), and neuropathy (nervous system damage), hearing impairment, Alzheima and CVD burden a person suffering from diabetes with emotional, physical and psychological pains (Strine *et al.*, 2005). Common symptoms of diabetes neuropathy is pain in extremities. Symptoms of CVD associated with diabetes include chest pain to leg pain, to confusion and paralysis. Abbas and Archibald (2007) reported that significantly long-term disability and premature mortality have association with foot ulceration and infection. Regular and proper care of the foot is needed to prevent amputations which can lead to psychological pain and limited mobility.

2.8 Socioeconomic status and diabetes

Studies from high income countries have reported that depression among diabetics has association with socioeconomic status, marital status, and physical activity and chronic somatic diseases (Engum *et al.*, 2005; Safraj *et al.*, 2012). There is a relationship between psychosocial factors (including social isolation or support, coping styles, behaviour and job stress or strain), socioeconomic status and diabetics' depression (Lustman & Clouse, 2005; Golden *et al.*, 2008). Studies had attributed higher risk to people with lower socioeconomic status, also known as inverse social gradients (Engum *et al.*, 2005; Knol *et al.*, 2007). Nevertheless, there may be variation in the relationship depending on the socioeconomic context of the particular country. For instance, in Low-income countries LICs, higher socioeconomic status may be related to higher levels of chronic disease risk factors while the poor experience a double burden of infectious and chronic diseases according to the protracted polarised model of epidemiological transition (Fleischer *et al.*, 2008).

Studies show association between Socio-economic status (SES) at the individual level (e.g.: unemployment, education) and psychological comorbidity due to diabetes (Acosta *et al.*, 2010; Yang *et al.*, 2009; Youssef *et al.*, 2013). A study done in Syria by Kilzieh *et al.* (2008) showed that depression comorbidity with any chronic disease increase with lower socioeconomic status. Yang *et al.* (2009) also reported significant association between unemployment and psychological pain in diabetic patients. A study further show that households with low income or less wealthy were more likely to be depressed due to diabetes complications (Kilzieh *et al.*, 2008).

Furthermore, studies suggest an association between lower education and depression among diabetics. For instance, Mier *et al.* (2008) reported statistically significant association between diabetics educated up to secondary level and depression, diabetics with less than 5 years of education were more likely to be depressed (Zhang *et al.*, 2008). Also diabetics in Thailand with less than 12 years education were significantly more likely to be depressed (Thaneerat *et al.*, 2010). Finally, Yekta *et al.* (2010) reported that non-depressed diabetics in Iranian were more educated than depressed diabetic patients.

From Thailand, Thaneerat *et al.* (2010) reported statistically significant association between poor social support (especially family support) and diabetes-depression among people with diabetes. Furthermore, Zhang *et al.* (2008) reported negative correlation between depressive symptoms and social support in China.

2.9 Study approach

2.9.1 Study design

In some studies, indirect costs of diabetes primarily relate to losses in productivity due to presenteeism and absenteeism, early retirement due to diabetes, dependence on social benefits as well as cost related to premature mortality and costs borne by caregivers and family members (Kanavos, Aardweg & Schurer, 2012; Tagoe, 2012). Certain aspects of indirect cost - e.g. probabilities for absenteeism, early retirement and social benefit reliance - have been studied in greater depth in a recent Danish registry population (Sorensen 2009).

A study conducted in Ghana by Tagoe (2012) relied on two perspectives in determining the cost burden on households due to chronic illness. These were the cost-of-illness (COI) approach (Suhrcke et al., 2006) and “biographical disruption” (Bury, 1982). The cost-of-illness approach measures costs associated with ill-health by categorizing into direct (medical costs), indirect (Human Capital approach or value of loss of functional capabilities), and intangible (pain and suffering) costs. Meanwhile according to Bury (1982) ‘biographical disruption’ refers to disorders that illness cause to the sufferer. de-Graft Aikins (2005) explained this to mean a person’s inability to perform routine daily tasks - including self-care - which may create psychological strain thereby leading to social isolation.

Suhrcke *et al*’s. (2006) cost-of-illness (COI) models was considered most appropriate approach for this study. Other studies that have used this model include: Bahia et al. (2011) estimated costs of type 2 diabetes mellitus outpatient care in the Brazilian public health system; Malone et al. (1997) estimated cost of allergic rhinitis in the United States; Addo et al. (2013) estimated household costs of mental health care in Ghana; and Asare & Aikins (2014) estimated the health facility Cost Of buruli ulcer wound treatment in Ghana. The main components of this approach

are direct cost, indirect cost and intangible cost. Direct cost comprise of cost of medicine, laboratory test and other treatment cost; indirect cost measures value of lost productive hours; and intangible burden assesses pain and suffering. This approach is considered suitable because it allows for estimation of both direct and indirect costs of treatment and disease management as well as the physical and psychosocial dimensions.

Likert scale is commonly used to measure perceptions (Vogt, 1999). This type of scale involves close-ended questions using ordinal scales as the answer option in order to rate their responses to evaluative questions (Vogt, 1999). Likert scale is appropriate for this study because: it provides a balanced scale with an equal number of positive and negative categories (e.g. very poor, poor, neutral, good, very good); limit the number of point along the scale (usually 5 to 7 or fewer); and match responses to questions (e.g. strongly agree, agree, disagree, strongly disagree) (Gail & Artino, 2013). These characteristics are relevant to this study's objectives which in part seek to assess physical and psychological pain and suffering associated with diabetes disease, as well as classification of quality of life.

2.9.2 Socioeconomic status

An important aspect in community based studies is the assessment of socioeconomic status (SES). Usually the evaluation of SES of a person requires the categorization of the person in respect of defined variables such as, education, occupation, economic status, physical assets, social position etc. And some of these variables can be evaluated simultaneously.

There are several methods or scales for classifying different populations by socioeconomic status. For example: Rahudkar scale (1960), Udai Parikh scale (1964), Jalota Scale (1970), Kulshrestha scale (1972), Kuppuswamy scale (1976), Shrivastava scale (1978), Bharadwaj scale

2001(Rahudkar, 1960; Parikh, 1964; Jalota et al., 1970; Kulshrestha & Day, 1972; Kuppuswamy, 1981; Srivastava, 1978; Bhardwaj, 2001). The key components of the above named models are education, occupation and income. However, changes in factors such as inflation, exchange rate, social transformation and fast growing economy have rendered these methods ineffective and less relevant in measuring the SES over the years. One most widely used scale for urban populations has been proposed by Kuppuswamy in India in 1976. However, getting a correct and reliable data on income especially in developing countries, including Ghana, is challenging. Hence, this study rely on principal component analysis approach to determining the SES of study patients.

Principal component analysis (PCA) is a multivariate technique that analyzes a data table I which observations are described by several inter-correlated quantitative dependent variables. PCA is very versatile, it is the oldest and remains the most popular technique in multivariate analysis (Grattan-Guinness, 1997). In addition, PCA can also be interpreted as a neural network model (Diamantaras & Kung, 1996; Abdi et al., 1999). Technically, a principal component can be defined as a linear combination of optimally- weighted observed variables. Mathematically, PCA depends on eigen-decomposition (SVD) of rectangular matrices (Abdi & Williams, 2010).

2.9.3 Sensitivity analysis

Sensitivity analysis (SA) is the process of testing the robustness of the study's conclusions to variations in the various assumptions made in the course of the analysis, changing the value of some parameters, variables and/or model structure in a meaningful way to examine the influence of these changes on the study results. A sensitivity analysis involves assessment of whether changes in some of the key costs estimates would affect the conclusions to be drawn from the

baseline analysis. It focuses on those costs or effects about which there is some uncertainty (Drummond et al., 1987; Drummond et al., 2005).

There are three main types of SA, namely: (1) *One-way sensitivity analysis*, conducted by changing one parameter at a time, and recalculating results; (2) *Multi-way sensitivity analysis*, conducted by changing more than one parameter simultaneously; and (3) *Threshold analysis*, calculates the critical values beyond which the conclusions of the analysis change. SA enables: (1) testing of robustness of results – i.e. helps assess whether the results are robust over a range of circumstances, thus strengthening the validity of the conclusions; (2) identification of key variables – i.e. helps identify which parameters and which values are most influential in the model; (3) building of accuracy and reliability into model – i.e. helps build accuracy and reliability into the analysis. This is particularly important when the analysis uses a model to assess programme costs; (4) direct future research – i.e. helps identify data gaps, which allows one to set a research agenda for meeting the established information needs (Drummond et al., 1987; Drummond et al., 2005).

Based on a similar academic research done on household cost of seeking diabetic healthcare in Ghana (Kumi-Ampofo, 2015), this study used one-way and multi-way SA by adjusting cost of medication and wages by 3%, 5% and 7%. Wage rate and medicine cost were varied because of uncertainty surrounding those cost data.

2.10 Conclusion

It was apparent that the dire consequences that diabetes and its accompanying complications place on people living with the disease cannot be underestimated. The disease places a lot of economic burden on individuals and affects their quality of life. It could be observed from the

literature review that studies cited were mainly from developed countries. Thus, very limited studies exist on the burden posed by type-2 diabetes mellitus on individuals living with the disease especially in Low and Middle Income Countries (LMIC). This study therefore becomes relevant as it will not only bridge the knowledge gap in the area but also provide useful information on the economic burden of type-2 diabetes mellitus in Ghana for individuals and policy makers in the health sector. The Ghana Non-communicable Disease Control Programme (NCDCP) confirmed the need for this study. Cost-of-illness approach is considered appropriate for this study.



CHAPTER THREE

METHODS

This chapter describes the research methods and design used in the study, the setting and context under which the study was conducted as well as the target population of the study. It further explains various steps for collecting data as well as ethical considerations observed.

3.1 Study area

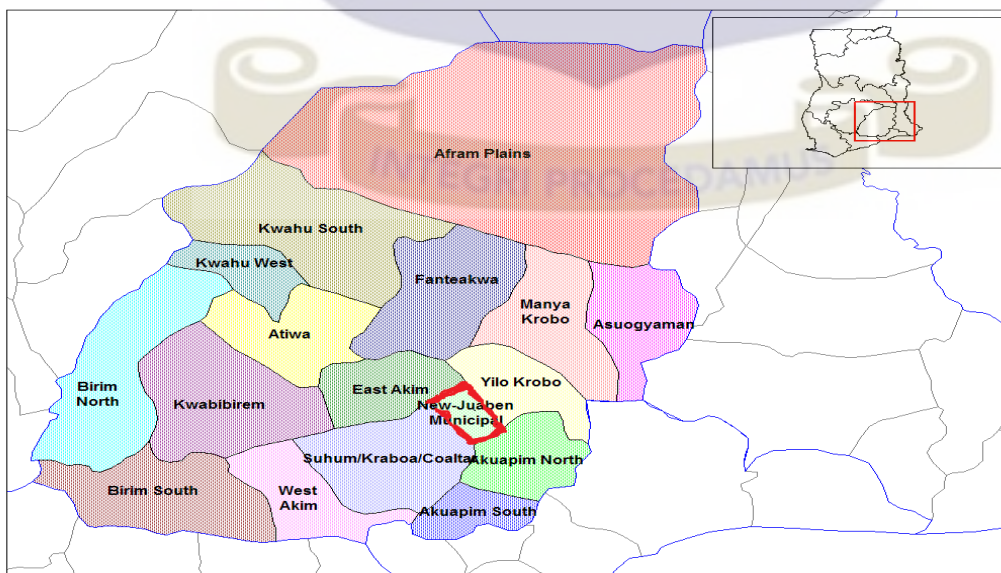
The study was carried out in New Juaben Municipal in the Eastern Region of Ghana. Figure 2 shows map of Eastern Region and New Juaben Municipal. The Municipality is one of the twenty-one districts in the Eastern Region. It covers an estimated area of 110 square kilometers constituting 0.57% of the total land area of Eastern Region and is bounded to the north by East-Akim Municipality, to the west by Suhum Kraboa Coalta District, to the east and south by Akuapim North District. The Municipality has a population of 159,369 (51.5% female and 48.5% males) with a growth rate of 2.6% (Eastern Regional Health Directorate, 2012). Koforidua, which is the regional capital is also the municipal.

Most of the administrative, commercial, political, social and economic activities are concentrated in the capital resulting in the influx of population to the municipality. The economy of the area is divided into three sectors, namely agriculture, industrial and the service sectors. Most of the economic activities are agro-based with agriculture constituting about 28.1%, industry 27.0% and service 44.5%.

There are a total of 51 health facilities in the municipality. These are: 1 government hospital; 2 Christian Health Association of Ghana (CHAG) hospitals; 3 clinics; 9 health centers; 3 private maternity homes; and 27 functional Community-based Health Planning and Services (CHPS)

zones. The Eastern Regional Hospital which was the study site serves as a referral specialist's hospital offering specialist medical and surgical care such as: visceral surgery; paediatric surgery; obstetrics and gynaecology; paediatrics and neonatology; internal medicine; dermatology; venereology and HIV medicine; radiology; dentistry; ear nose and throat, ophthalmology; rehabilitation and; laboratory medicine. One of the five major causes of Out-Patients-Department (OPD) attendance at the hospital was diabetes. The Eastern Regional Hospital's Diabetic Clinic is the biggest in the region and caters for about 140 patients a week. The regional hospital recently introduced appointment procedure to help curb the situation where patients had to come to the hospital at dawn or a night before and queue only to consult a doctor. The main diabetics' appointment days are Wednesdays and Thursdays though the clinic operates throughout the week except for weekends. Payment for health service delivery is both by insurance (national and private) and out-of-pocket. About 92 per cent of the clients of the hospital were registered with the National Health Insurance Scheme compared to about 62% of the regional population as at 2013.

Figure 2: Map of New Juaben Municipal



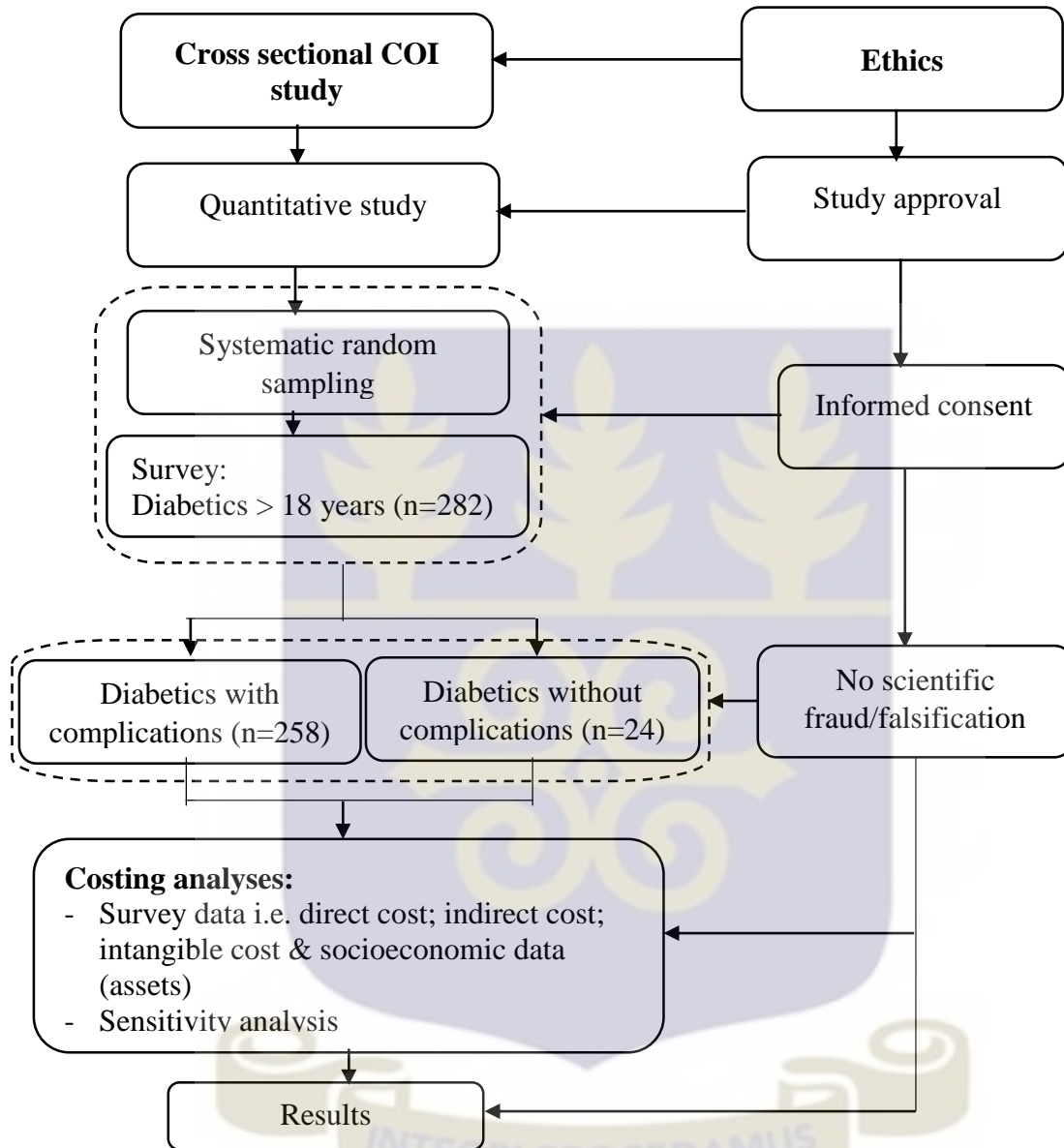
3.2 Study Design

This study is a descriptive cross sectional cost-of-illness study which relied on quantitative data. Data were collected from sampled type-2 diabetes patients attending the Eastern Regional Hospital Diabetic Clinic from 4th to 26th May, 2016 (Figure 3). The study relied on systematic random sampling technique. Thus, with a sample size of 270 diabetics and study population (within the period of data collection) estimated to be 560, sampling fraction was worked, and a sample interval of 2 was obtained. The first random number selected between 1 and 2 was 1. Hence, the sample selected each day of data collection was 1, 3, 5, 7, 9 etc. That is, on each diabetic clinic day within the period of data collection, approximately half of diabetes patients waiting in a queue for treatment were recruited in a manner such that every second patient is excluded. When a selected patient did not meet the inclusion criteria or refused to participate, the next eligible patient was recruited for interview. Overall fieldworkers sampled 282 diabetics which comprise of those with complications (n=258) and patients without complications (n=24) above 18years. The sampled patients were consented and interviewed using structured close-ended questionnaire. Figure 3 shows diagrammatic representation of study design.

Inclusion criteria: Patients with type-2 diabetes of age more than 18 years who attended the Eastern Regional Hospital Diabetics Clinic between 4th to 26th May, 2016.

Exclusion criteria: Diabetes patients below 18 years who attended the Eastern Regional Hospital Diabetics Clinic during the period of the data collection.

Figure 3: Study design of economic burden of type-2 diabetes mellitus



3.3 Sample size

From previous academic research done on household cost of seeking diabetic healthcare in the Tano North District of the Brong Ahafo region in Ghana, the mean household cost of seeking diabetes healthcare was GH¢ 146.70 (SD= GH¢79.78) (Kumi-Ampofo, 2015). With this study's

outcome of interest being continuous quantitative variable, the sample size was calculated as follows:

$$n = \left[\frac{z_{\alpha/2} \sigma}{E} \right]^2$$

Where:

n is sample size, $z_{\alpha/2}$ is Critical z-value (1.96), σ is Standard deviation of cost of diabetes treatment in Ghana (GH¢79.78), E : Margin of error around the average costs to be estimated (GH¢10.00).

$$\Rightarrow n = \left(\frac{1.96 * 79.78}{10.00} \right)^2 = \frac{(156.37)^2}{100} = \frac{24451.58}{100}$$

$$n = 245$$

Adjusting for 10% non-response rate,

$$\begin{aligned} &\Rightarrow 245 \times 0.1 \\ &= 25 \end{aligned}$$

Hence,

Total sample size (N) = sample size (n) + 10% non-response

$$\begin{aligned} \Rightarrow N &= 245 + 25 \\ &= 270 \end{aligned}$$

Therefore the sample size determined for this study was approximately 270.

3.4 Study variables

The outcome variable was economic burden of type-2 diabetes mellitus. The explanatory variables were direct, indirect and intangible costs of type-2 diabetes mellitus. Table 1 shows the variables of interest for this study.

Table 1: Study variables

| Cost type | Cost variable | Cost description |
|------------------|----------------------|--|
| Direct cost | Medical | <ol style="list-style-type: none"> 1. Cost of consultation 2. Cost of diagnostics 3. Cost of treatment 4. Cost of medication |
| | Non-medical | <ol style="list-style-type: none"> 1. Travel cost 2. Cost of diet 3. Other subsistence expenses |
| Indirect cost | Productivity lost | <ol style="list-style-type: none"> 1. Work hours lost 2. Lost wages |
| Intangible cost | Intangible burden | <ol style="list-style-type: none"> 1. Physical pain 2. Psychological pain 3. Social isolation 4. Anxiety 5. Stress 6. Depression 7. Stigmatization 8. Self-esteem 9. Other quality of life measures |

3.5 Quality control

Training of fieldworkers

The field workers used for the study were trained prior to the commencement of the data collection. The training focused on: (1) ensuring that the field workers understood the objectives of the study; (2) building understanding on the survey tools and interpretation; (3) assessing capacity of field workers to perform the survey tasks. Simulated practice was done to build consensus and consistency on study tool understanding, interpretation and administration.

Pre-test of data collection tools

The data collection tool was pretested to ensure that: the study tool reflected local conditions; questions were clearly understood to elicit accurate responses by the patients; and tool is well

formatted. The pre-test was carried out at the University of Ghana Hospital Diabetic Clinic. Necessary modifications to the data collection tool was made based on the pre-test. During data collection, the Principal Investigator supervised field workers and thoroughly crosschecked data collected for accuracy and consistency.

3.6 Data collection

Through interviews, data were collected from a total of 282 diabetics at a response rate of 100%. Data collected included demographics, cost, socioeconomics, household asset and quality of life information using structured questionnaire. Some information were retrieved electronically from patients' records. Cost data collected included direct medical cost (i.e. consultation fee, diagnosis, drugs etc.); direct non-medical cost (i.e. travel cost, diet and other cost), indirect cost (i.e. lost productive work hours and lost wages). Intangible burden data collected included information on physical pain, psychological pain, anxiety, stress, social isolation and self-esteem. On a scale of one to five, the study patients were also asked to rate their quality of life. Other information collected included functional household assets owned by study participants. Experienced research assistants were used in the data collection to ensure data quality. Table 2 shows summary of data collection techniques and tools.

3.7 Data entry and analysis

Cost data were entered into Microsoft Excel version 2013. Study participants' Likert scale responses to intangible burden associated with diabetes mellitus was entered into Epi Info Version 10. The entries were done by two independent data entry clerks. To prevent data entry errors, the completed questionnaires were coded, double entered and cleaned. Detected discrepancies were resolved by consulting the original completed questionnaires.

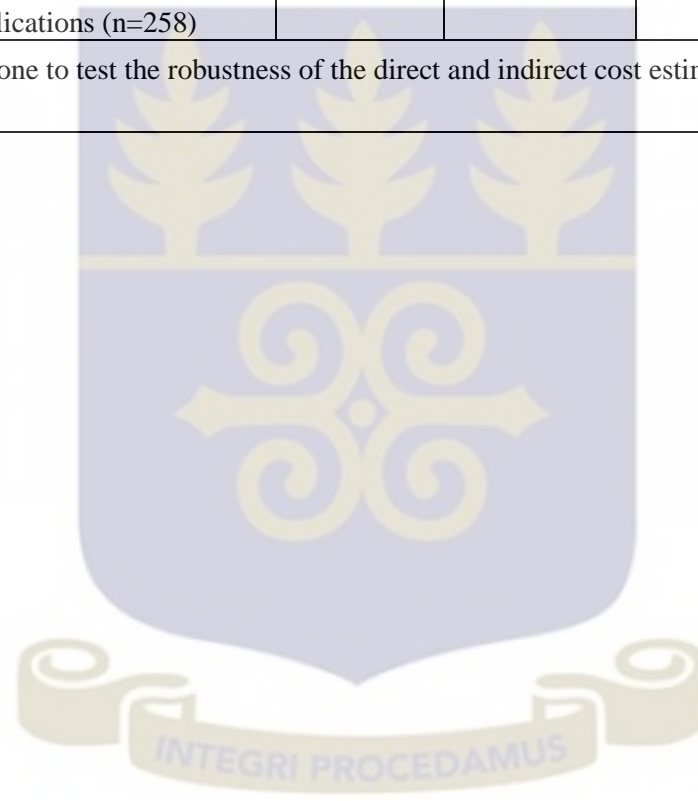
Direct medical cost, direct non-medical cost and indirect cost incurred by diabetics was estimated using Microsoft Excel version 2013 and STATA version 13. Total direct cost was estimated by summing total direct medical cost and total direct non-medical cost. Indirect cost was estimated by multiplying productive work hours lost and average lost wage. Total cost was estimated by summing direct and indirect cost. All costs data was presented in total aggregates, averages, median and percentage share of cost profile. Table 2 shows summary of data analysis techniques. The Likert scale responses to intangible burden associated with diabetes were analysed using STATA version 13 and expressed in percentages. The results were presented using charts, graphs and figures. Results of patients' assessment of quality of life was presented in a radar chart.

For study participants' socioeconomic status (SES) determination, wealth index was constructed from household asset data using principal components analysis. By this, categorical variables used for assets ownership was transformed into separate dichotomous (0-1) indicators. Common factor score for each participant was produced based on the asset indicators. Wealth quintiles (i.e. lowest, second, middle, fourth and highest) was then obtained by assigning score to each respondent, ranking each study participant by his or her score, and then dividing the ranking into five equal categories, each comprising 20 percent of the total patients. Total direct and indirect treatment cost of diabetics was then sorted and classified by wealth quintiles or socioeconomic status with the aid of STATA Version 13.

Table 2: Summary of Data Collection Techniques, Tools and Analysis

| # | Specific Objective | Variable | Sampling procedure/approach | Data Collection Technique | Tools | Source of Data | Type of data Analysis |
|---|--|---|--|---------------------------|--------------------------|---|---|
| 1 | Determine the proportion of type-2 diabetic complications. | Diabetes complication | Systematic random sampling of diabetics above 18 years (n=282). 8.5% diabetics with complications (n=24) and 91.5% diabetics without complications (n=258) | Face-to-face interviews | Structured questionnaire | Eastern Regional Hospital Diabetic Clinic | Descriptive analyses (mean, frequencies & proportions) using EpiInfo Version 10 and STATA Version 13. |
| 2 | Estimate the direct treatment cost of type-2 diabetes mellitus. | Direct medical cost; Direct non-medical cost | Systematic random sampling of diabetics above 18 years (n=282). 8.5% diabetics with complications (n=24) and 91.5% diabetics without complications (n=258) | Face-to-face interviews | Structured questionnaire | Eastern Regional Hospital Diabetic Clinic | Direct medical cost: sum all cost on medical consultation, diagnostic test, treatment and medication incurred due to the diabetes. Direct nonmedical cost: sum all cost on travelling, diet and other subsistent cost incurred due to the diabetes. Total direct cost: sum of direct medical and non-medical cost incurred due to the diabetes illness. These calculations were done using Microsoft Excel version 13 and STATA version 13. |
| 3 | Estimate the indirect treatment cost of type-2 diabetes mellitus. | Indirect cost (Productivity lost) | Systematic random sampling of diabetics above 18 years (n=282). 8.5% diabetics with complications (n=24) and 91.5% diabetics without complications (n=258) | Face-to-face interviews | Structured questionnaire | Eastern Regional Hospital Diabetic Clinic | Estimated based on Human Capital Approach (or Income Approach) i.e. output or productivity losses based on total work hours lost due to the diabetes and average earnings. Thus, total work hours lost due to diabetes multiplied by average hourly earnings yielded total indirect treatment cost estimate. This calculation was done using Microsoft Excel version 13 and STATA version 13. |
| 4 | Estimate the total treatment cost of type-2 diabetes mellitus by socioeconomic status. | Direct medical cost; Direct non-medical cost; Indirect cost (Productivity lost) | Systematic random sampling of diabetics above 18 years (n=282). 8.5% diabetics with complications (n=24) and 91.5% diabetics without complications (n=258) | Face-to-face interviews | Structured questionnaire | Eastern Regional Hospital Diabetic Clinic | Total direct and indirect treatment cost of diabetics was sorted and classified by wealth quintiles with the aid of STATA Version 13. |

| # | Specific Objective | Variable | Sampling procedure/approach | Data Collection Technique | Tools | Source of Data | Type of data Analysis |
|--|---|-------------------|--|---------------------------|--------------------------|---|---|
| 5 | Determine intangible cost associated with type-2 diabetes mellitus. | Intangible burden | Systematic random sampling of diabetics above 18 years (n=282). 8.5% diabetics with complications (n=24) and 91.5% diabetics without complications (n=258) | Face-to-face interviews | Structured questionnaire | Eastern Regional Hospital Diabetic Clinic | Study participants' Likert scale responses to physical pain, psychological pain, anxiety, stress, social isolation, self-esteem and other quality of life components related to diabetes was analyzed using STATA Version 13. |
| <p>Further analysis: Sensitivity Analysis was done to test the robustness of the direct and indirect cost estimates by adjusting costs of medications and wages by 3%, 5% and 7%.</p> | | | | | | | |



Direct medical cost: This was estimated by summing all the cost incurred by patients due to the diabetes disease and its related complications on medical goods and services e.g. consultation, diagnostic test and medication. Table 3 shows estimation approach for direct medical cost of diabetes mellitus treatment in this study.

Table 3: Estimation of direct medical costs

| Cost Type | Costs Estimation Approach |
|--------------------|--|
| Consultation | Summation of cost of consultation and registration of diabetics during study period |
| Diagnostics | Summation of cost of diagnostic tests request for diabetics during study period |
| Treatment | Summation of cost of treatment received by diabetics during study period |
| Medication | Summation of cost of medications prescribed for diabetics during study period |
| Total medical cost | Summation of total costs of consultation, diagnostics, treatment and medications for diabetics during study period |

Direct non-medical cost: This was estimated by summing non-medical goods and services e.g. travelling cost, diet and other subsistent cost due to the diabetes illness and its related complications and comorbidities. Table 4 shows estimation approach for direct non-medical cost of diabetes mellitus treatment in this study.

Table 4: Estimation of direct non-medical costs

| Cost Type | Estimation Approach |
|-------------------------------|--|
| Travel | Summation of all travel costs incurred by diabetics travelling to and from the hospital |
| Diet | Summation of all costs incurred by diabetics on food items purchased due to the diabetes disease during study period |
| Miscellaneous | Summation of all other costs incurred by diabetics on other items due to the diabetes disease |
| Total direct non-medical cost | Summation of all travel cost, all cost on diet and all miscellaneous expenses incurred by sampled diabetics |

Total direct cost: This was a summation of estimated direct medical and non-medical cost incurred due to the diabetes illness and its related complications due to comorbidities.

Indirect cost: Estimation of indirect cost was based on Human Capital Approach (or Income Approach). This was an estimate of output or productivity losses based on total work hours lost and total lost average earnings due to the diabetes disease and its associated complications. Table 5 shows estimation approach for indirect cost of diabetes mellitus treatment in this study.

Table 5: Estimation of indirect costs

| Cost Category | Estimated Approach |
|-----------------------------|--|
| Productive days lost | Summation of total number of lost work hours by employed diabetics |
| Valued productive days lost | This was estimated by multiplying total number of work hours lost by employed diabetics in the last month, and the daily minimum wage. |
| Total indirect cost | This was estimated valued productive days lost |

Intangible cost: analysis of intangible burden was descriptive using Likert scale and quality of life measurements. Patients' physical and psychological pain, anxiety, stress, social isolation and other quality of life components due to the diabetes disease was assessed. Responses were counted and expressed in frequencies, percentages, graphs and charts.

3.8 Sensitivity Analysis

Sensitivity Analysis was done to test the robustness of the cost estimates by varying costs of medications and wages. This estimated total cost taking into account the time values associated with costs of diabetes care by adjusting cost of medication and wages by 3%, 5% and 7%. The percentages relied upon was from a similar academic research done on household cost of seeking

diabetic healthcare in Ghana (Kumi-Ampofo, 2015). Wage rate and medicine cost were varied because of uncertainty surrounding those cost data.

3.9 Ethical considerations

Ethical clearance

Ethical approval was sought from the Ethical Review Committee of the Ghana Health Service (Ethical Approval–ID No: GHS-ERC: 13/12/15). Permission from the Eastern Regional Health Directorate, New Juaben Municipal Health Directorate and the In-charges of the Eastern Regional Hospital was sought. Informed consent was obtained from sampled diabetic patients and confidentiality/privacy assured before their engagement in the study. They were informed about the purpose, procedures, risks and benefits of participating in the study. Study participants were told that there were no risk involved in participating in the study. The participants were however informed of possible minor discomforts in answering certain questions for which they may choose not to answer. For participants who could not read, the consent form was read out and explained to them in the presence of an independent witness. Only participants who agreed to be part of the study were recruited for the study and required to sign or thumbprint a consent form as an indication of their willingness to participate.

The participants were informed that there would be no consequences, forfeiting of healthcare or other benefit if they choose to withdraw from the study. Study participants were given sugar free biscuits at the completion of the interview as a token of appreciation for their time spent answering the research questions.

Data collected for the study was kept confidential and used solely for the purpose indicated for the study. Data files were password protected. Hard copy and electronic data were stored securely in locked file cabinets without the names of the participants, and access was limited to

the Principal Investigator and the supervisors of the study. Interviews and extraction of data from patients' records were done only by trained Research Assistants and Principal Investigator.

Participants were informed that participation in the study was voluntary and they could withdraw from the study at any time without attracting any penalty. Participants were not coerced into taking part in the study.



CHAPTER FOUR

RESULTS

This chapter presents the study results. The segments of the results section are: background characteristics of study patients, health state of study patient; direct treatment cost of type-2 diabetes mellitus; indirect treatment cost of type-2 diabetes mellitus; intangible cost associated with type-2 diabetes mellitus; and total treatment cost of type-2 diabetes mellitus by socioeconomic status.

4.1 Background Characteristics of study diabetics

Table 6 shows the socio-demographic background characteristics of both type-2 diabetics with complications and those without complications involved in this study. The mean age of the patients was 58 years (95% CI: 44-72) and majority of the patients (n=190) (67.4%) were above 55 years. Most of the patients (n=175) (67.8%) above 55 years had complications. Only about (n=18) 6.4% were below 35 years. The bulk of the patients were females (n=225) (79.8%) compared to males (n=57) (20.2%). Furthermore, majority of the patients attained at least basic education (n=167) (59.3%) whereas 19.5% had no form of education. Also, 10.6% (n=30) had secondary and tertiary level education each. About 47.2% (n=133) of the patients were married whilst 32.3% (n=91) were widowed. More than 15% were either divorced or separated and 5.3% had never been married. More than half of the patients (51.8%) (n=145) were employed. There was no significant difference in employment status of diabetics with complication and those without complications. For those unemployed, it was mainly due to diabetes (n=5) (4%). About 2% (n=3) of the patients were students, 4% (n=5) were housewives and 29% (n=39) were retired. Most of the patients were traders (n=72) (53.1%) and about 19% (n=26) were farmers. Others such as accountants, businessmen, teachers and drivers constituted 29.9% (n=39).

As shown in table 6, majority of the patients earned less than GHS500.00 (USD128.21) monthly and barely 5.6% earned more than GHS1,000 (USD256.41). The average income earned by patients was GHS509.80 (95% CI: 0-1,399.10). Employed diabetics spent an average of GHS179.62 (95% CI: 0-615.57) on healthcare compared to unemployed diabetics who spent on average GHS138.40 (95% CI: 0-297.20). Furthermore, most of the type-2 diabetes study patients who had complications (48.4%) (n=12) were unemployed due to their condition compared to those without complications (50%) (n=12).

Table 6: Socio-demographic characteristics of study patients

| Item | Diabetes patients (N=282) | | |
|--------------------------|---------------------------|---------------------------|-------------------|
| | Complication (N=258) | No complication (N=24) | Total n (%) |
| | n (%) | n (%) | |
| Age (years) | | | |
| <35 | 14 (5.5) | 4 (16.7) | 18 (6.4) |
| 35-45 | 15 (5.8) | 2 (8.3) | 17 (6.0) |
| 45-55 | 54 (20.9) | 3 (12.5) | 57 (20.2) |
| >55 | 175 (67.8) | 15 (62.5) | 190 (67.4) |
| <i>Mean (95% CI)</i> | <i>58 (45-71)</i> | <i>54 (37-71)</i> | <i>58 (44-72)</i> |
| Sex | | | |
| Male | 51 (19.8) | 6 (25.0) | 57 (20.2) |
| Female | 207 (80.2) | 18 (75.0) | 225 (79.8) |
| Educational level | | | |
| No education | 49 (19.0) | 6 (25.0) | 55 (19.5) |
| Basic school | 158 (61.2) | 9 (37.5) | 167 (59.3) |
| Secondary | 24 (9.3) | 6 (25.0) | 30 (10.6) |
| Tertiary | 27 (10.5) | 3 (12.5) | 30 (10.6) |
| Marital status | | | |
| Married/living together | 121 (46.9) | 12 (50.0) | 133 (47.2) |
| Divorced/ Separated | 40 (15.5) | 3 (12.5) | 43 (15.2) |
| Widowed | 85 (33.0) | 6 (25.0) | 91 (32.3) |
| Never married | 12 (4.6) | 3 (12.5) | 15 (5.3) |
| Employment status | | | |
| Employed | 133 (51.6) | 12 (50.0) | 145 (51.8) |
| Unemployed | 125 (48.4) | 12 (50.0) | 135 (48.2) |

| Item | Diabetes patients (N=282) | | |
|--|---------------------------|-----------------------|--------------------|
| | Complication | No complication | Total |
| | (N=258) n (%) | (N=24) n (%) | n (%) |
| Occupation | | | |
| Trading | 72 (54.1) | 5 (41.7) | 77 (53.1) |
| Farmer | 25 (18.8) | 3 (25.0) | 28 (19.3) |
| Other | 36 (27.1) | 4 (33.3) | 40 (27.6) |
| Average monthly income (from all sources) | | | |
| < GHS 300 | 96 (37.2) | 8 (33.3) | 104 (36.0) |
| GHS300-500 | 37 (14.3) | 1 (4.2) | 38 (13.5) |
| GHS500-100 | 67 (26.0) | 9 (37.5) | 76 (27.9) |
| > GHS1000 | 13 (5.0) | 0 | 13 (4.6) |
| Non-response | 45 (17.4) | 6 (25.0) | 51 (18.1) |
| <i>Mean</i> | <i>517.23</i> | <i>422.22</i> | <i>509.8</i> |
| <i>(95% CI)</i> | <i>(454.11-580.35)</i> | <i>(93.13-751.31)</i> | <i>(0-1,399.1)</i> |

US\$1.00 equivalent to GHS3.90 (Bank of Ghana average monthly interbank exchange rate, June 2016)

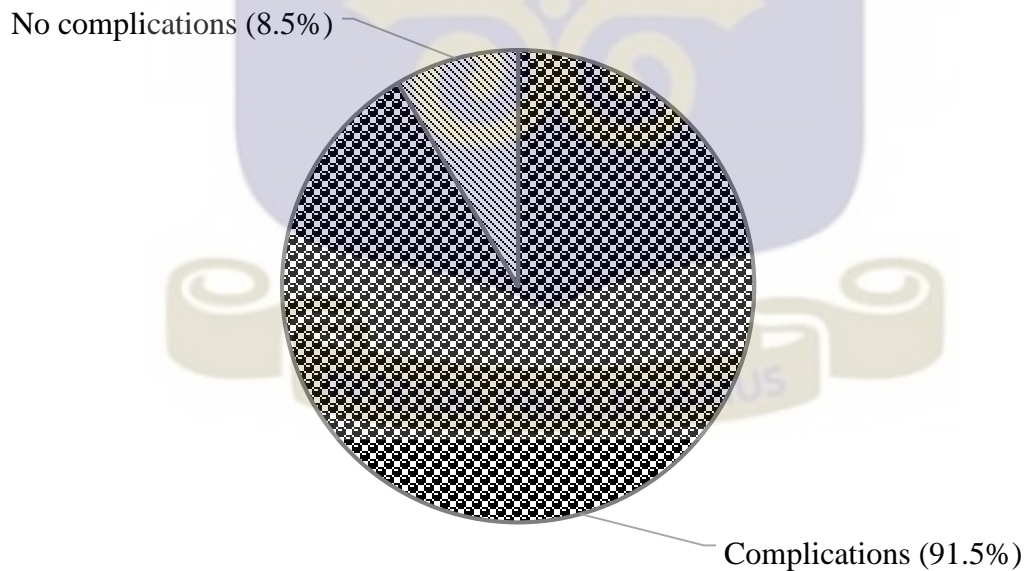
4.2 Health status of study patient

Over 91% (n=258) of patients were suffering from complications, in some cases multiple complications (Figure 4). Overall, the mean number of years that study patients had been diagnosed with diabetes was 8 years (95% CI: 1-15). While about 32.5% (n=91) had been diagnosed with diabetes between 6 -10 years, 46.8% (n=131) and 20.7% (n=58) had been diagnosed with diabetes for less than 5 years and more than 10 years respectively. While the average years of diagnose for diabetics with complications was 8 years (95% CI: 1-15), that of those without complications was 5 years (95% CI: 1-9). Majority of patients (79.3%) (n=211) had their fasting blood sugar level above normal level of 6.1mmol/dL. The mean fasting blood sugar level of study patients was 9mmol/L (95% CI: 5.1-12.9). About 80% (n=206) of diabetics with complication had their fasting blood sugar level above normal level compared to 70% (n=17) of patients without complication. The mean fasting blood sugar level of diabetics with

complication was 9.1mmol/dL (95% CI: 5.1-13.1), which was slightly higher than the overall average. Meanwhile the mean for patients without complication was 0.9mmol/dL less than the overall average.

Generally, type-2 diabetics unlike type-1 diabetics are supposed to be non-insulin dependent. Type-2 diabetics rely on treatment arrangement which include oral medication, exercise and dietary plan. This notwithstanding, more than half of the studied diabetics (51.2%) (n=144) were insulin dependent. Reasons ascribed to the usage of insulin by the study hospital were: (1) it is standard practice of study facility to use insulin to normalise severely high glucose levels of type-2 diabetics; (2) patients' resistance to medication over time (e.g. average years study diabetics had been diagnosed with disease in this study was 8years); and (3) to supplement patients' medication in order to keep glucose at normal levels and prevent complication or risk.

Figure 4: Distribution of type-2 diabetes patient by health status



4.3 Direct Treatment Cost of Type-2 Diabetes Mellitus

The direct cost was made up of two main components i.e. estimated direct medical and direct non-medical cost incurred by both diabetics with complications and those without complication due to the diabetes illness and its related comorbidities.

4.3.1 Direct medical cost

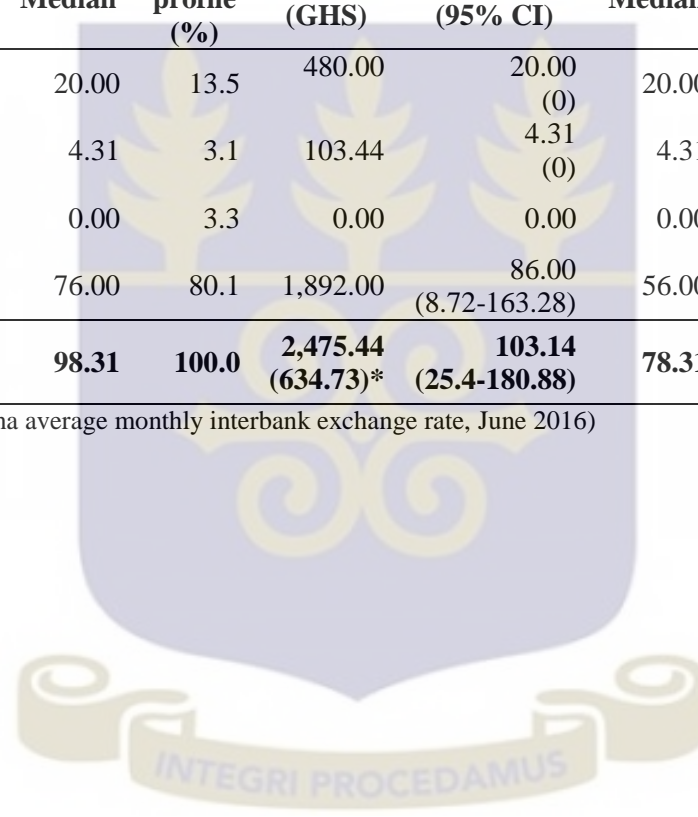
The components of direct medical costs were consultation, laboratory test, medicine and other treatment. Table 7 shows distribution of direct medical cost by study diabetics' health status. Medicine cost constituted a bulk of total direct medical cost profile of diabetes health care for both those with complication (80.1%) (GHS30,289.00) and those without complications (76.4%) (GHS1,892.00). Diabetics suffering complications spent an estimated GHS30,289.00 on medicine whereas those without complications spent GHS1,892.00. The mean medicine costs were GH¢122.63 (95% CI: 0-469.29) and GHS86.00 (95% CI: 8.72-163.28) respectively for diabetics with complications and those without complications. Consultation cost recorded the second highest share of the cost profile with a mean of GHS19.80 (95% CI: 17.95-21.65) for those with complication and GHS20.00 for those without complications. The total direct medical cost estimated was GHS37,819.10 (USD9,697.21) for complicated diabetics with a mean of GHS146.59 (95% CI: 0-492.24) and GHS2,475.44 (USD634.73) for non-complicated diabetics with a mean of GHS103.14 (95% CI: 25.4-180.88).

As shown in Table 7, overall, medicine cost constituted about 80% of the total direct medical cost profile. The overall estimated direct medical cost was GHS40,294.54 (USD10,331.93) with a mean of GHS142.89 (95% CI: 0-474.42).

Table 7: Direct medical cost

| Cost item | Diabetes patients (N=282) | | | | | | | | Total cost estimate | | |
|--------------|--|------------------------------------|--------------|------------------|-------------------------------------|---------------------------------------|--------------|------------------|---|------------------------------------|------------------|
| | Complication (n=258) | | | | No complication (n=24) | | | | Cost (GHS) | Mean (95% CI) | Cost profile (%) |
| | Cost (GHS) | Mean (95% CI) | Median | Cost profile (%) | Cost (GHS) | Mean (95% CI) | Median | Cost profile (%) | | | |
| Consultation | 5,108.62 | 19.80 (17.95-21.65) | 20.00 | 13.5 | 480.00 | 20.00 (0) | 20.00 | 19.4 | 5,588.62 | 19.81 (18.4-21.58) | 13.9 |
| Lab tests | 1,166.48 | 4.52 (1.46-7.58) | 4.31 | 3.1 | 103.44 | 4.31 (0) | 4.31 | 4.2 | 1,269.92 | 4.50 (1.6-7.4) | 3.2 |
| Treatment | 1,255.00 | 5.02 (0-72.00) | 0.00 | 3.3 | 0.00 | 0.00 | 0.00 | 0.0 | 1,255.00 | 4.60 (0-644.6) | 3.1 |
| Medicines | 30,289.00 | 122.63 (0-469.29) | 76.00 | 80.1 | 1,892.00 | 86.00 (8.72-163.28) | 56.00 | 76.4 | 32,181.00 | 119.60 (0-452.60) | 79.9 |
| TOTAL | 37,819.10 (9,697.21)* | 146.59 (0-492.24) | 98.31 | 100.0 | 2,475.44 (634.73)* | 103.14 (25.4-180.88) | 78.31 | 100.0 | 40,294.54 (10,331.93)* | 142.89 (0-474.42) | 100.00 |

*US\$1.00 equivalent to GHS3.9 (Bank of Ghana average monthly interbank exchange rate, June 2016)



4.3.2 Direct non-medical cost

The components of direct non-medical costs were travel cost, food cost and miscellaneous. Distribution of direct medical cost among diabetics with complications and those without complications is presented in Table 8. More than half of the total non-medical cost profile composed of travel cost. That is, for diabetics with complications, it constituted over 60% whereas for patients without complications it constituted about 51% of the total direct non-medical cost profile. The total direct non-medical cost estimated for type-2 diabetics with complication was GHS4,367.60 with a mean of GH16.93 (95% CI: 1.82-32.04) whilst that estimated for patients without complications was GHS455.40 with a mean of GH18.98 (95% CI: 6.08-31.88).

Table 8 shows that the total estimated non-medical cost was GHS4823.00 (USD1,236.67). Travel cost constituted major part of the direct non-medical cost (59.8%) and recorded a mean cost of GHS10.2 (95% CI: 0-22.5). Food cost formed 34.6% of the cost profile whilst miscellaneous cost contributed 5.6%.

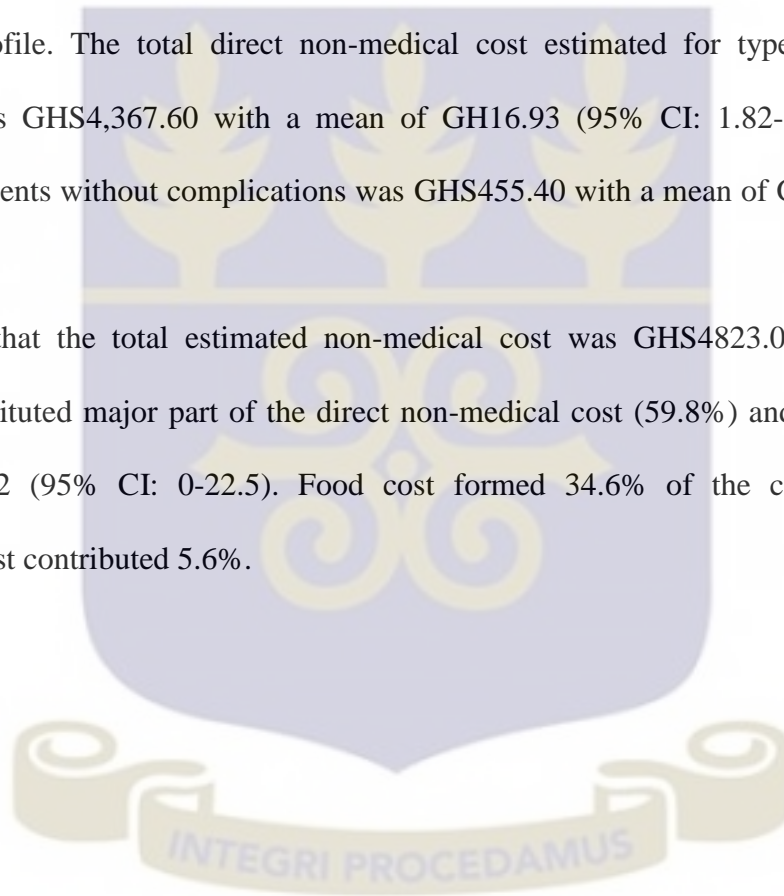
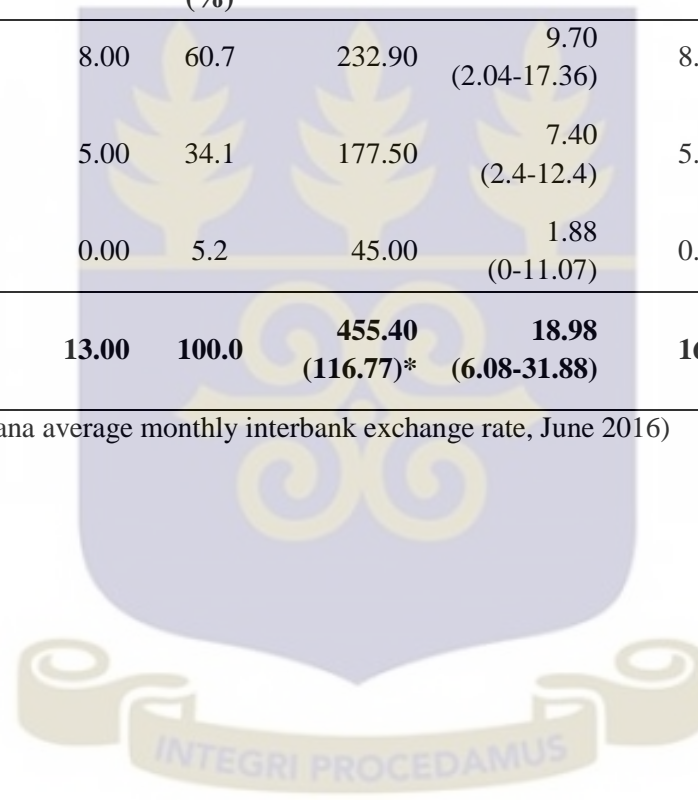


Table 8: Direct non-medical cost

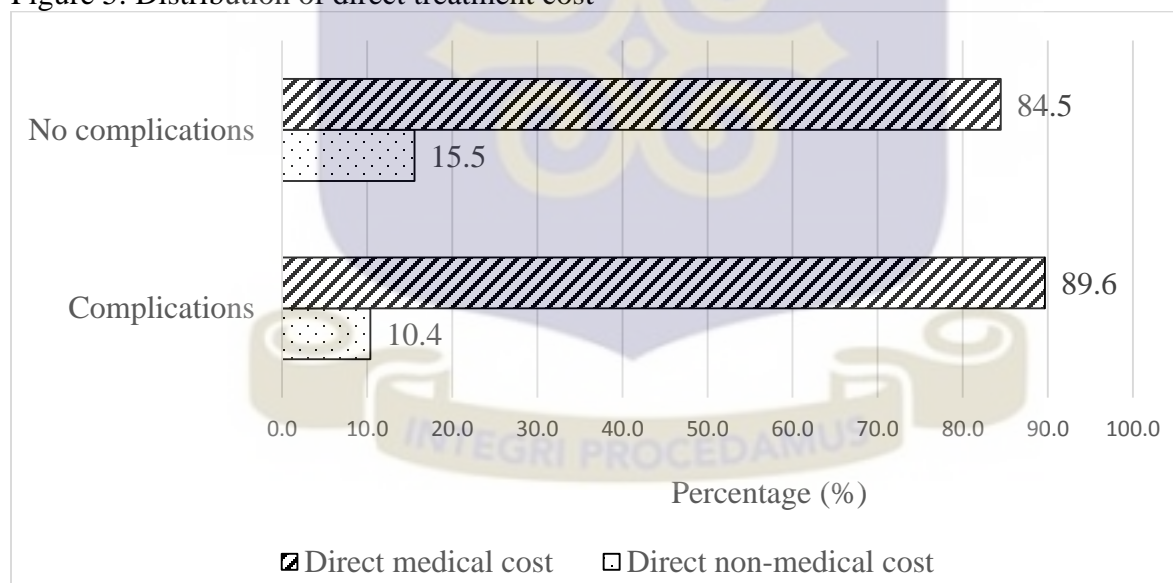
| Cost item | Diabetes patients (N=282) | | | | | | | | Total cost estimate | | |
|---------------|---------------------------------------|-------------------------------------|--------------|------------------|-----------------------------------|-------------------------------------|-------------|------------------|-------------------------------------|---|------------------|
| | Complication (n=258) | | | | No complication (n=24) | | | | Cost GHS | Mean (95% CI) | Cost profile (%) |
| | Cost GHS | Mean (95% CI) | Median | Cost profile (%) | Cost GHS | Mean (95% CI) | Median | Cost profile (%) | | | |
| Travel cost | 2649.9 | 10.27 (0-22.97) | 8.00 | 60.7 | 232.90 | 9.70 (2.04-17.36) | 8.00 | 51.1 | 2,882.80 | 10.2 (0-22.5) | 59.8 |
| Food cost | 1491.20 | 5.78 (1.38-10.18) | 5.00 | 34.1 | 177.50 | 7.40 (2.4-12.4) | 5.00 | 39.0 | 1,668.70 | 5.9 (1.4-10.4) | 34.6 |
| Miscellaneous | 226.5 | 0.92 (0-5.95) | 0.00 | 5.2 | 45.00 | 1.88 (0-11.07) | 0.00 | 9.9 | 271.50 | 1.0 (4.5-6.5) | 5.6 |
| Total | 4,367.60 (1,119.90)* | 16.93 (1.82-32.04) | 13.00 | 100.0 | 455.40 (116.77)* | 18.98 (6.08-31.88) | 16.5 | 100.0 | 4823.00 (1236.67)* | 1,236.67 (1221.75-1251.59) | 100.0 |

*US\$1.00 equivalent to GHS3.9 (Bank of Ghana average monthly interbank exchange rate, June 2016)



The total direct cost estimate was made up of direct medical and non-medical costs. It is the sum of total direct medical cost and total direct non-medical cost. Table 9 presents an amalgamation of the direct medical and non-medical costs estimated in Tables 7 and 8 above. The total direct treatment cost estimated for type-2 diabetics suffering complications and comorbidities was GHS42,186.70 (US\$10817.10) whereas that for patients without complications was GHS2,930.84 (US\$751.50). The mean costs were GHS163.51 (95% CI: 0-508.97) and GHS 122.12 (95% CI: 43.77-200.47) for complicated diabetics and non-complicated diabetics respectively indicating that patients with complications have higher cost burden compared to those without complications. Furthermore, the median for diabetics suffering complication was GHS110.51 whilst that of patients without complication was GHS103.31. Figure 5 shows the percentage distribution of direct cost by diabetics' health status.

Figure 5: Distribution of direct treatment cost



The estimated total direct cost of type-2 diabetes treatment was GHS45,117.54 (US\$11,568.60). There was a vast difference in the distribution of percentage share of total direct cost profile between direct medical and non-medical costs. That is total direct medical cost is about eight

times direct non-medical cost. The percentage share of direct medical costs in relation to overall total direct cost profile was about 89%. Again the percentage share of medicine (71.3%) far outweighs the combined percentage share of the other cost components (26.8%). Thus, it can be inferred that the dominance of direct medical cost on direct total cost was largely influenced by medicine cost. The mean direct medical cost was GHS142.89 (95% CI: 0-474.42) whereas that of direct non-medical cost was GHS17.10 (95% CI: 2.18-32.02) and overall total direct cost was GHS159.99 (95% CI: 0-491.33). Details of direct medical cost estimates and profile is contained in Table 9.



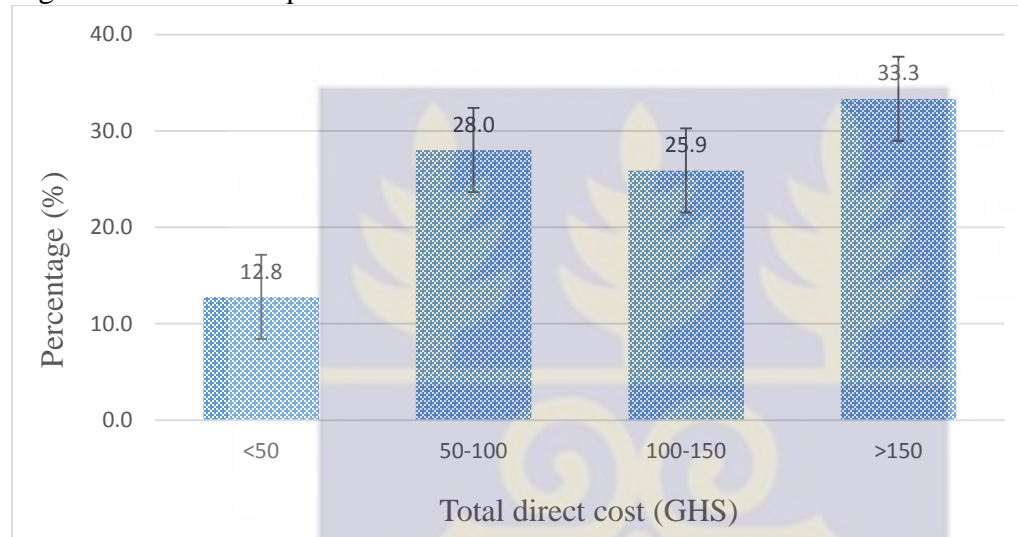
Table 9: Total direct cost of type-2 diabetes mellitus

| Cost Component | Diabetes patients (N=282) | | | | | | Total cost estimate | | |
|--------------------------------|---|-------------------------------------|---------------|-------------------------------------|--|---------------|---|---|------------------|
| | Complication (n=258) | | | No complication (n=24) | | | Cost (GHS) | Mean (95% CI) | Cost profile (%) |
| | Cost (GHS) | Mean (95% CI) | Median | Cost (GHS) | Mean (95% CI) | Median | | | |
| Direct medical cost | | | | | | | | | |
| Consultation | 5,108.62 | 19.80 (17.95-21.65) | 20.00 | 480.00 | 20.00 (0) | 20.00 | 5,588.62 | 19.81 (18.4-21.58) | 12.4 |
| Lab tests | 1,166.48 | 4.52 (1.46-7.58) | 4.31 | 103.44 | 4.31 (0) | 4.31 | 1,269.92 | 4.50 (1.6-7.4) | 2.8 |
| Treatment | 1,255.00 | 5.02 (0-72.00) | 0.00 | 0 | 0.00 | | 1,255.00 | 4.60 (0-644.6) | 2.8 |
| Medicines | 30,289.00 | 122.63 (0-469.29) | 76.00 | 1,892.00 | 86.00 (8.72-163.28) | 56.00 | 32,181.00 | 119.60 (0-452.60) | 71.3 |
| Sub-total | 37,819.10 | 146.59 (0-492.24) | 98.31 | 2,475.44 | 103.14 (25.4-180.88) | 78.31 | 40,294.54 | 142.89 (0-474.42) | |
| Direct non-medical cost | | | | | | | | | |
| Travel cost | 2649.9 | 10.27 (0-22.97) | 8.00 | 232.90 | 9.70 (2.04-17.36) | 8.00 | 2,882.8 | 10.2 (0-22.5) | 6.4 |
| Food cost | 1491.20 | 5.78 (1.38-10.18) | 5.00 | 177.50 | 7.40 (2.4-12.4) | 5.00 | 1,668.7 | 5.9 (1.4-10.4) | 3.7 |
| Miscellaneous | 226.5 | 0.92 (0-5.95) | 0 | 45.00 | 1.88 (0-11.07) | 0.00 | 271.5 | 1.0 (4.5-6.5) | 0.6 |
| Sub-total | 4,367.60 | 16.93 (1.82-32.04) | 13.00 | 455.40 | 18.98 (6.08-31.88) | 16.5 | 4,823.00 | 1,236.67 (1221.75-1251.59) | |
| Total Direct Cost | 42,186.70 (10,817.10)* | 163.51 (0-508.97) | 110.51 | 2,930.84 (751.50)* | 122.12 (43.77-200.47) | 103.31 | 45,117.54 (11,568.60)* | 159.99 (0-491.33) | 100.0 |

*US\$1.00 equivalent to GHS3.9 (Bank of Ghana average monthly interbank exchange rate, June 2016)

A few of the type-2 diabetes patients (12.8%) (n=36) spent less than GHS50.00 on average on direct cost of seeking healthcare whilst 28% (n=79) spent between GHS50.00 to GHS100.00 per month. However, about one-third (n=94) of study patients spent over GHS150.00 per month on healthcare (Figure 6).

Figure 6: Patients' expenditure on total direct cost of diabetes healthcare

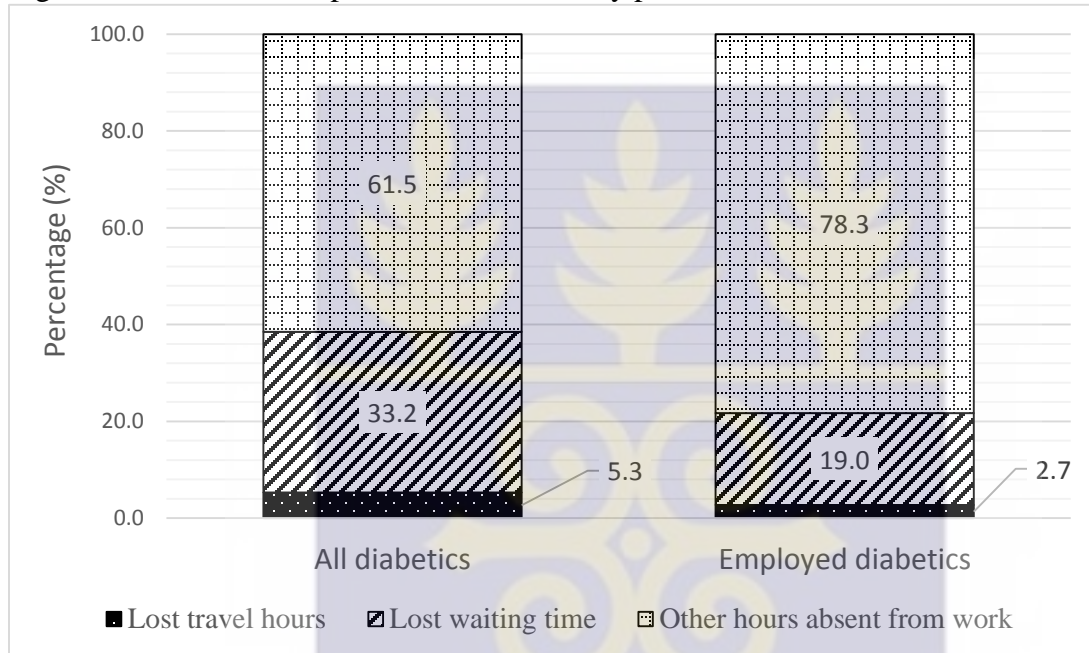


4.4 Indirect Treatment Cost of Type-2 Diabetes Mellitus

The indirect cost estimated the productive work hours lost due to diabetes by using the human capital approach. Figure 6 shows the percentage distribution of total time spent travelling to and from diabetic clinic by both employed and unemployed diabetics, productive work time lost by employed diabetics and total waiting time spent at the diabetes clinic seeking health care by both employed and unemployed diabetics. Both diabetics with complications and those without complications lost over 70% of the estimated productive work time due absenteeism. The percentage work time lost in the month preceding patients' clinic visit in relation to overall time – both employed and unemployed – spent on diabetes disease management was 61.5%, followed by waiting time at the hospital for treatment (33.3%) and travel time to-and-from the hospital

(5.3%). On the other hand, the overall work time lost by employed diabetics due to the disease constituted more than 78% of their total diabetes disease management time. Furthermore, 19% of the total productive lost hours was attributable to waiting time at the hospital to receive medical care followed by 2.7% of travel time (Figure 7).

Figure 7: Distribution of productive time lost by patients



The indirect cost estimation was done for only productively engaged (employed) diabetics. The total productive days lost by employed type-2 diabetics was 437. The valuation of productive time lost to patient relied on the national minimum wage per day of GHS8.00 as at June, 2016 (Ministry of Finance and Economic Planning, June 2016). The total productive days lost by diabetics with complications was 390days whereas that of patients without complications was 47days. The valued productive time lost by diabetics with complication was GHS2,464.00 (US\$631.79) whereas that of patients without complication was 272.00 (US\$69.74).

Overall, the value of time absent from productive work within past month was estimated as 2,736.00 (US\$701.53). The mean indirect cost was GHS36.00 (95% CI: 0-120.08). The total indirect cost estimated was 3,496.00 (US\$896.41) (Table 10).



Table 10: Total indirect cost of diabetes disease

| Category | Item | Diabetes patients (N=145)*** | | | | Total cost estimate |
|------------------|------------------|---------------------------------|---|------------------------|--|---|
| | | Complication (n=133) | | No complication (n=12) | | |
| | | Productive days lost | Valued productive days lost** (GHS) | Productive days lost | Valued productive days lost** (GHS) | Valued productive days lost** (GHS) |
| Health seeking | Travel time | 10 | - | 2 | - | - |
| | Waiting time | 72 | - | 11 | - | - |
| Work absenteeism | Absent from work | 308 | 2,464.00 | 34 | 272.00 | 2,736.00 |
| Total | | 390 | 2,464.00 (US\$631.79)* | 47 | 272.00 (US\$69.74)* | 2,736.00 (US\$701.53)* |

Mean=36.69; 95% CI: 0-120.08; Median=10.00

***Estimation done for only employed diabetics based on work absenteeism

**National minimum wage per day of GHS8.00 was used to value lost productivity (Ministry of Finance, June 2016)

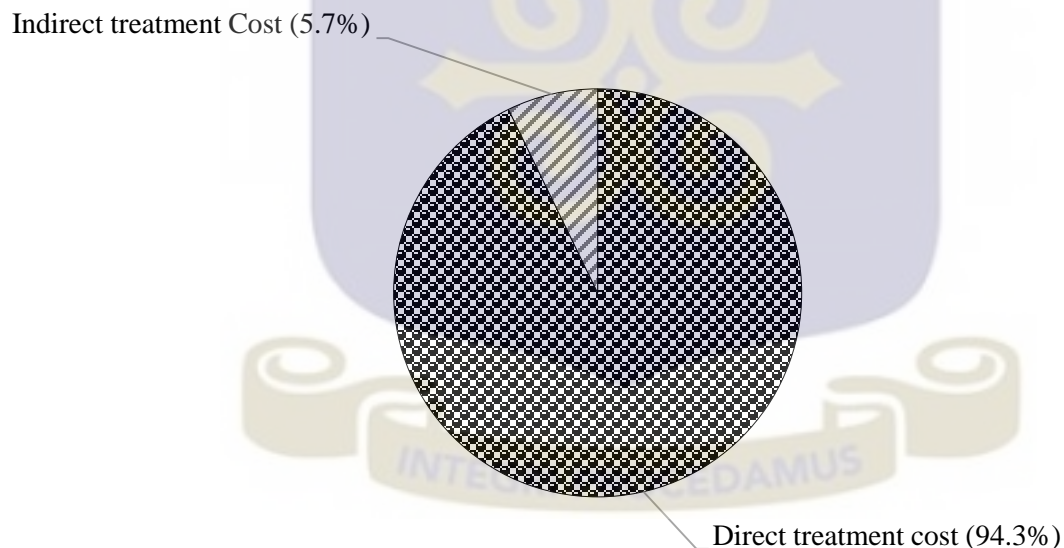
*US\$1.00 equivalent to GHS3.90 (Bank of Ghana average monthly interbank exchange rate, June 2016)



4.5 Total treatment cost of type-2 diabetes mellitus

The total treatment cost of type-2 diabetes estimate summed direct cost and indirect cost. As shown in Table 11 the total treatment cost for diabetics with complications was estimated as GHS44,650.70 (US\$11,448.90) with mean of GHS175.61 (95% CI: 0-429.55) and median of GHS124.31. The total treatment cost of diabetics healthcare was GHS3,202.84 (US\$821.24) for diabetics without complications with mean of GHS137.77 (95% CI: 53.93-221.61) and median of GHS111.31. The overall estimated total cost of diabetes treatment – for diabetics with complications and those without complication together - was GHS47,853.54 (US\$12,270.14). Figure 8 presents percentage distribution of treatment cost. Direct cost constituted the bulk of the total treatment cost profile (94.3%).

Figure 8: Distribution of total treatment cost



The high percentage share of direct cost to total treatment cost can largely be attributed to the influence of medicine cost over the total treatment cost. That is, medicine cost alone constituted over 66% of the total treatment cost profile. The mean and median total cost were GHS184.45 (95% CI: 0-521.58) and GHS128.89 respectively.

Table 11: Total cost of type-2 diabetes mellitus

| Cost component | Total cost estimates | | | Cost profile (%) |
|--------------------------------|--|-------------------------------------|---|------------------|
| | Complication (GHS) | No Complication (GHS) | Total Cost (GHS) | |
| <u>Direct Cost</u> | | | | |
| Direct medical cost | | | | |
| Consultation | 5,108.62 | 480.00 | 5,588.62 | 11.7 |
| Lab tests | 1,166.48 | 103.44 | 1,269.92 | 2.7 |
| Treatment | 1,255.00 | 0 | 1,255.00 | 2.6 |
| Medicines | 30,289.00 | 1,892.00 | 32,181.00 | 67.2 |
| Sub-total | 37,819.10 | 2,475.44 | 40,294.54 | - |
| Direct non-medical cost | | | | |
| Travel cost | 2649.9 | 232.90 | 2,882.80 | 6.0 |
| Food cost | 1491.20 | 177.50 | 1,668.70 | 3.5 |
| Miscellaneous | 226.5 | 45.00 | 271.50 | 0.6 |
| Sub-total | 4,367.60 | 455.40 | 4,823.00 | - |
| Total Direct Cost | 42,186.70 | 2,930.84 | 45,117.54 | - |
| <u>Indirect Cost</u> | | | | |
| Absent from work | 2,464.00 | 272.00 | 2,736.00 | 5.7 |
| Total Indirect Cost | 2,464.00 | 272.00 | 2,736.00 | - |
| Total Cost | 44,650.7 (11,448.90)* | 3,202.84 (821.24)* | 47,853.54 (12,270.14)* | 100.0 |

*US\$1.00 equivalent to GHS3.90 (Bank of Ghana average monthly interbank exchange rate, June 2016)

4.6 Total Treatment Cost of Type-2 Diabetes Mellitus by Socioeconomic Status

Further analysis was done to assess the distribution of total treatment cost among patients by socioeconomic status. There was significant variation in the total treatment cost of type-2 diabetes health care across the various socioeconomic groupings. Table 13 shows distribution of total treatment cost by wealth quintiles and disease state. There were quite observable differences in the total cost. Patients in the fourth wealth quintile recorded the highest total treatment cost among both diabetics with complication and those without complications. That is the total

treatment cost for complicated diabetics was GHS11,145.75 with a mean of GHS214.34 (95% CI: 0-674.11) while that of non-complicated diabetics was GHS656.93 with a mean of GHS131.30 (95% CI: 38.04-224.56). Patients with complications in the highest wealth quintile recorded the lowest share of the total cost profile while diabetics without complications in the lowest wealth quintile recorded the lowest share.

Table 12 further shows distribution of total treatment cost among various diabetics' socioeconomic groupings. Patients who fell in the fourth wealth quintile spent an estimated GHS11,069.75 which constituted the highest of the total cost profile with a mean of GHS214.34 (95% CI: 0-928.66). The percentage share of estimated total treatment cost for patients in the lowest group was 17.1% compared to those in the highest group which was about 16.5% representing the lowest. Diabetics in the second and middle wealth quintiles accounted for 22% and 20% of the total treatment cost profile respectively and their means were GHS194.06 (95% CI: 0-436.43) and GHS177.37 (95% CI: 58.63-296.11) respectively.

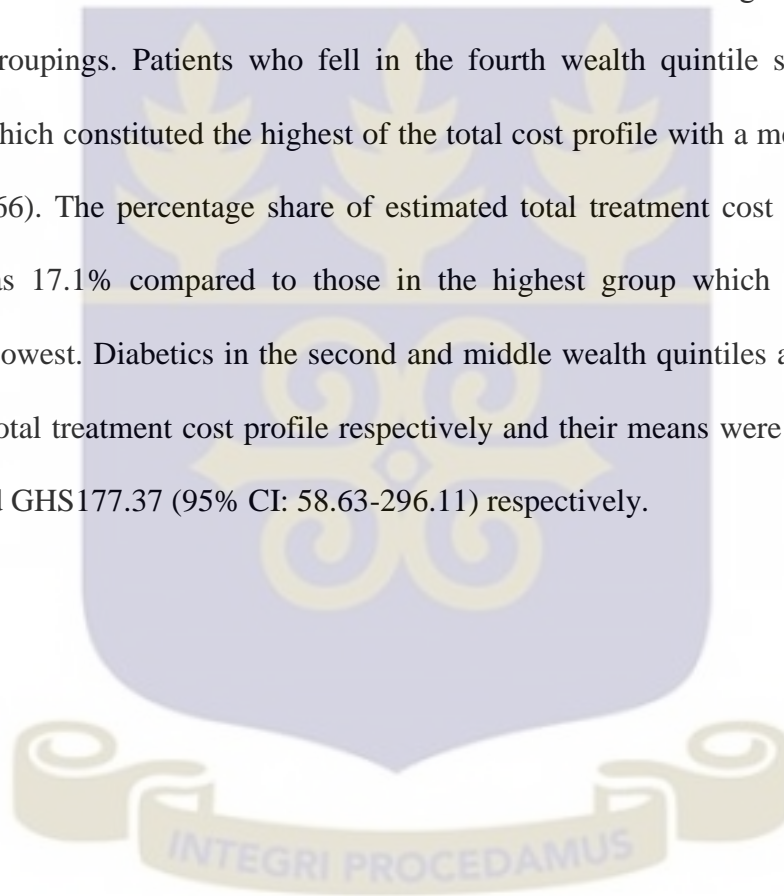


Table 12: Total treatment cost by socioeconomic status and disease status

| Wealth quintile | Diabetes patients (N=282) | | | | | | Total cost estimate | | |
|-----------------|--|------------------------------------|---------------|------------------------------------|--|---------------|--|------------------------------------|------------------|
| | Complication (n=258) | | | No complication (n=24) | | | Cost (GHS) | Mean (95% CI) | Cost profile (%) |
| | Cost (GHS) | Mean (95% CI) | Median | Cost (GHS) | Mean (95% CI) | Median | | | |
| Lowest | 7,824.12 | 151.93 (0-318.78) | 108.64 | 379.05 | 91.01 (42.28-139.74) | 88.31 | 8,203.17 | 153.43 (0-312.50) | 17.1 |
| Second | 10,032.39 | 194.39 (0-440.56) | 149.71 | 513.90 | 117.98 (27.23-208.73) | 88.31 | 10,546.28 | 194.06 (0-436.43) | 22.0 |
| Middle | 8,791.18 | 173.87 (52.25-295.49) | 126.44 | 793.22 | 173.84 (80.58-267.10) | 115.56 | 9,584.40 | 177.37 (58.63-296.11) | 20.0 |
| Fourth | 11,069.75 | 214.34 (0-674.11) | 123.81 | 580.93 | 131.30 (38.04-224.56) | 108.31 | 11,650.68 | 243.87 (0-928.66) | 24.4 |
| Highest | 7,209.27 | 142.85 (57.79-227.91) | 124.31 | 659.74 | 183.94 (81.94-285.94) | 174.31 | 7,869.01 | 154.22 (69.31-239.13) | 16.5 |
| Total | 44,926.71 (11,519.67) | 175.61 (0-429.55) | 124.31 | 2,926.84 (750.47) | 137.77 (53.93-221.61) | 111.31 | 47,853.54 (12,270.14) | 184.45 (0-521.58) | 100.0 |

*US\$1.00 equivalent to GHS3.9 (Bank of Ghana average monthly interbank exchange rate, June 2016)



Furthermore, cost of health care played a major role in the health seeking behaviour of diabetes patients. Over 60% (n=48) of study patients skipped diabetes treatment because of costs associated with treatment of the disease. Likewise, about 7.5% (n=6) of study patients skipped treatment due to time spent at the hospital while 7.5% (n=6) skipped due to distance to the diabetic clinic. Also, while 12.5% missed treatment appointment because of work, 12.5% (n=10) missed treatment due to other reasons. Additional analysis was done on percentage of total income patients without insurance spent on their diabetes healthcare. It was observed that about 38% (n=86) of patients spent less than 25% of their total income as direct cost of diabetes care, 15.2% (n=34) spent between 50% - 75% income whereas 26.3% (n=59) spent more than 75% of their income. More than 41% (n=93) of patients who pay for health care directly out-of-pocket (OOP) spent more than half of their income doing so.

4.7 Sensitivity analysis of cost of Diabetes Mellitus

In order to test robustness of costs estimated, one-way (1-way) and multi-way (M-way) sensitivity analysis (SA) were done by varying relevant costs components. The components on which the sensitivity tests were conducted were medication and wage. These components were selected due to the presence of uncertainty associated with those items. The test was conducted by increasing the two cost components by 3%, 5% and 7% respectively.

As shown in Table 13 1-way SA conducted by varying the cost of medication by 3%, 5% and 7% yielded respectively 2.0%, 3.4% and 4.7% increases in total treatment cost of type two treatment cost. However, same analysis conducted on wage rate yielded percentage increases of 0.2, 0.3 and 0.4 respectively in total treatment cost. Also, while the 3%, 5% and 7% variations in medication respectively resulted in 0.1, 0.2 and 0.3 percentage increases in direct

cost, same level of variations in wage rate respectively resulted in 0.2, 0.3 and 0.4 percentage increases in indirect cost. Furthermore, concurrent variations in both medication and wage rate by 3%, 5% and 7% resulted in a percentage fall in direct cost in proportions to total treatment cost and thus a percentage rise in indirect cost in proportions to total treatment cost. However, there was 2.2, 3.6 and 5.1 percentage increases in total treatment cost respectively. The results of the sensitivity analysis (Tables 13) showed that this study's cost estimates were sensitive to changes in wage and medicine cost variables.



Table 13: Sensitivity analysis of total cost of diabetes disease management

| Scenario | Cost component | Percentage change in parameter | Total cost | Percentage change in total cost | Proportion of total cost | | Percentage change in proportions of cost | |
|---|--------------------------|--------------------------------|------------|---------------------------------|--------------------------|----------|--|----------|
| | | | GHS | | Direct | Indirect | Direct | Indirect |
| Base scenario | | 0 | 47,853.54 | 0.0 | 94.3 | 5.7 | 0 | 0 |
| Variation (One-way Sensitivity Analysis)* | Medication | 3 | 48,818.97 | 2.0 | 94.4 | 5.6 | 0.1 | -0.1 |
| | | 5 | 49,462.59 | 3.4 | 94.5 | 5.5 | 0.2 | -0.2 |
| | | 7 | 50,106.21 | 4.7 | 94.5 | 5.5 | 0.3 | -0.3 |
| Variation (One-way Sensitivity Analysis)* | Wage rate** | 3 | 47,935.62 | 0.2 | 94.1 | 5.9 | -0.2 | 0.2 |
| | | 5 | 47,990.34 | 0.3 | 94.0 | 6.0 | -0.3 | 0.3 |
| | | 7 | 48,045.06 | 0.4 | 93.9 | 6.1 | -0.4 | 0.4 |
| Multi-variation (Multi-way Sensitivity Analysis)* | Medication and Wage rate | 3 | 48,901.05 | 2.2 | 94.2 | 5.8 | 0.0 | 0.0 |
| | | 5 | 49,599.39 | 3.6 | 94.2 | 5.8 | -0.1 | 0.1 |
| | | 7 | 50,297.73 | 5.1 | 94.2 | 5.8 | -0.1 | 0.1 |

US\$1.00 equivalent to GHS3.9 (Bank of Ghana average monthly interbank exchange rate, June 2016)

*The cost of medication and wage rate was independently and concurrently varied by 3%, 5% and 7% increment.

**The national minimum wage per day of GHS8.00 as at June, 2016 was used to value productivity days and time lost to patients

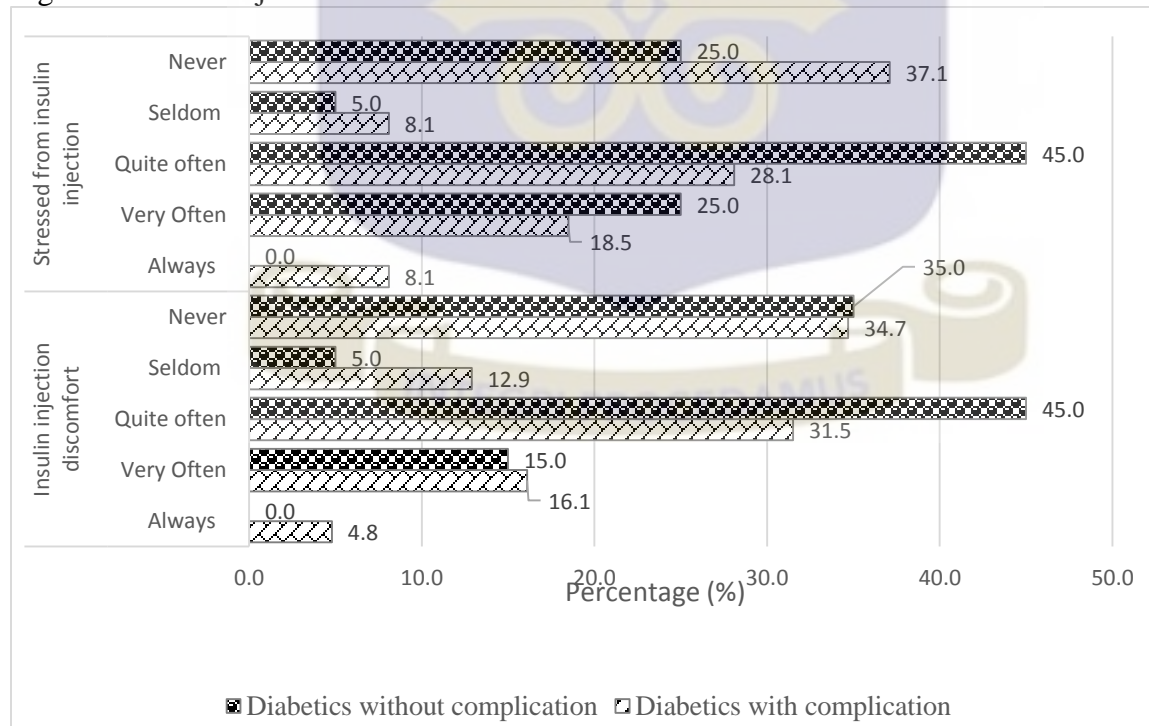
4.8 Intangible Cost associated with Type-2 Diabetes Mellitus

The intangible cost assesses the incalculable burden – usually physical and psychological pain and suffering - associated with the diabetes disease. The elements assessed was categorised into physical and psychological effect, social effect, work related effect and quality of life assessment.

4.8.1 Physical and psychological effect

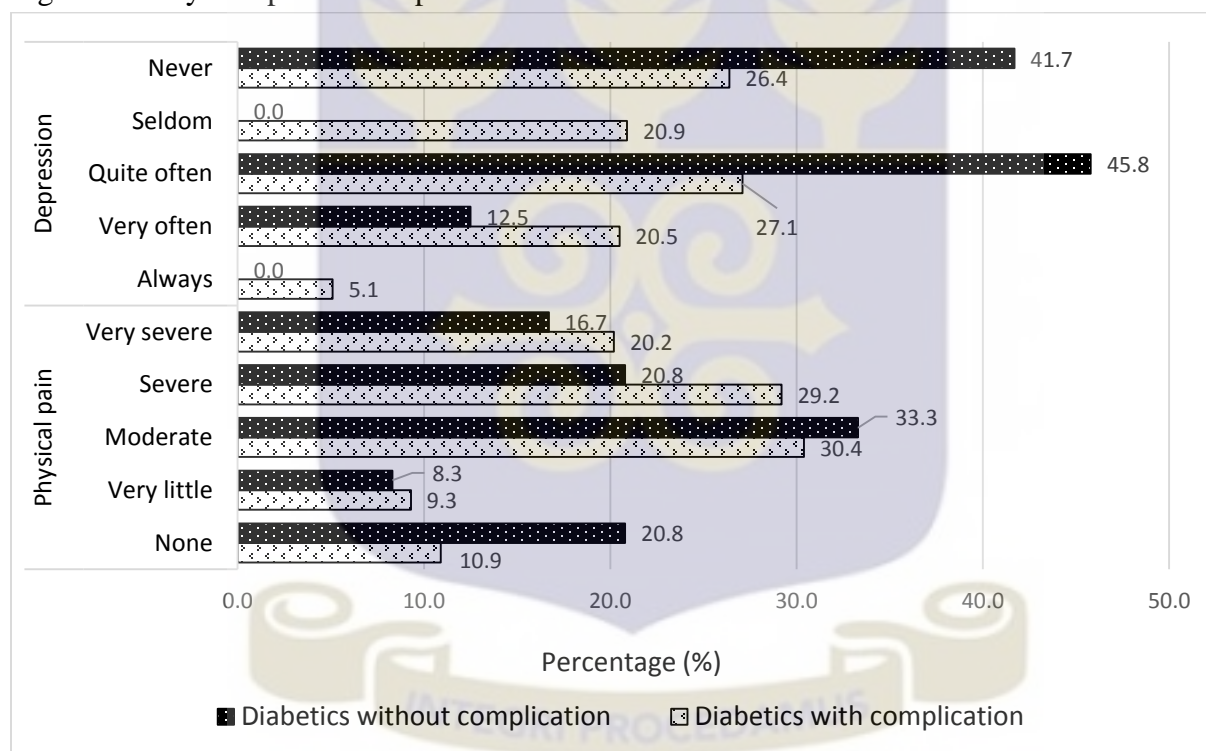
The physical and psychological pain endured by study diabetics is presented in Figures 9, 10 and 11. As observed in Figure 9, higher percentage of diabetics without complications (45%) (n=9) who used insulin quite often felt stressed than those with complications (28.1%) (n=35). Also higher percentage of diabetics without complications (45%) (n=9) who used insulin quite often felt uncomfortable than those with complications (31.5%) (n=39).

Figure 9: Insulin injection effect



About 42% (n=10) of diabetics without complications never felt depressed compare to about 26% (n=68) of patients who have complications. However, greater percentage of diabetics without complications (45.8%) (n=11) quite often felt depressed compared to those with complications (27.1%) (n=70). Higher percentage of complicated diabetics (20.2%) (n=52) suffered very severe physical pains than non-complicated diabetics (16.7%) (n=4). Furthermore, while about 21% (n=5) diabetics without complications felt no physical pains, about 11% (n=28) of patients with complications felt no pains (Figure 10).

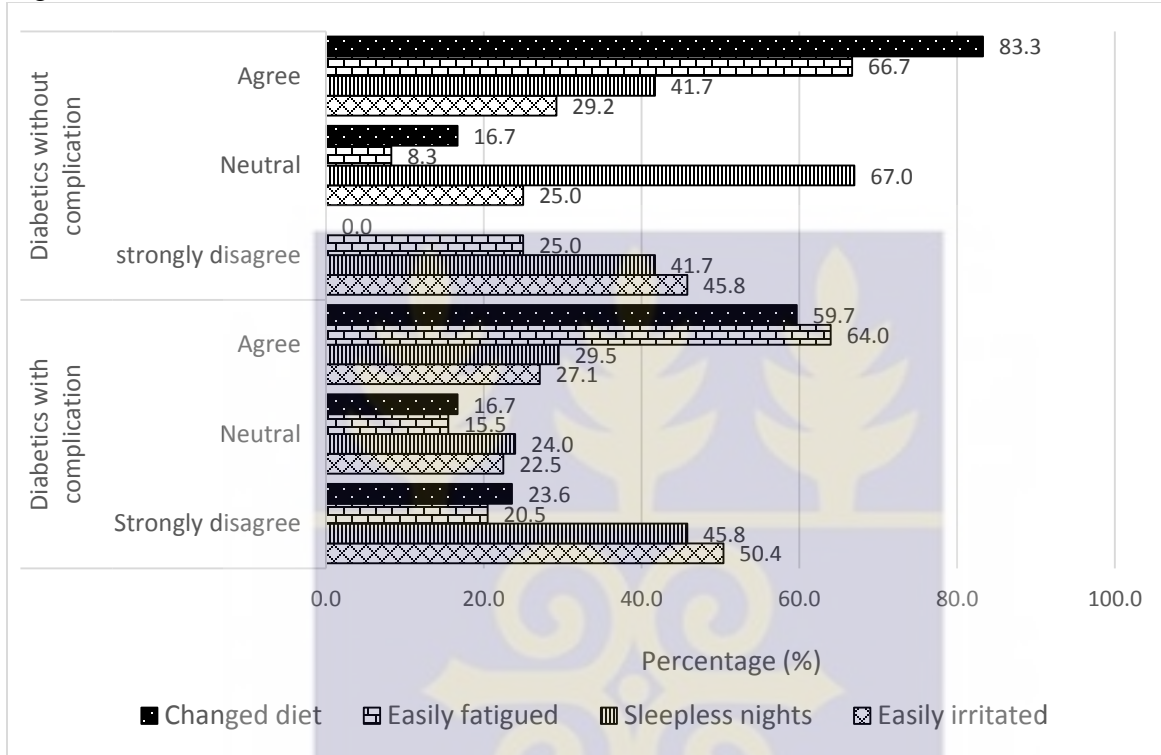
Figure 10: Physical pain and depression due to diabetes illness



As observed in Figure 11, a greater percentage of patients with complications (59.7%) (n=154) and without complications (83.3%) (n=20) agreed they had changed diet due to their diabetes illness. Furthermore, 64% (n=165) of complicated diabetics and about 67% (n=16) of non-complicated diabetics were easily fatigued because of their diabetes disease. Also, less than half

of both diabetics with complications and those without complications neither had sleepless nights nor easily felt irritated.

Figure 11: Emotional stress due to diabetes illness



4.8.2 Social effect

Overall about 44% (n=124) of patients had their marriages affected by the diabetes conditions one way or the other. Out of this number, while 25% (n=31) of patients divorced due to their diabetes illness, 9.2% (n=11) separated. Other effects mainly included quarrel over financial stress posed by cost of diabetes healthcare and sexual weakness (Figure 12).

Figure 12: Diabetes effect on marriage

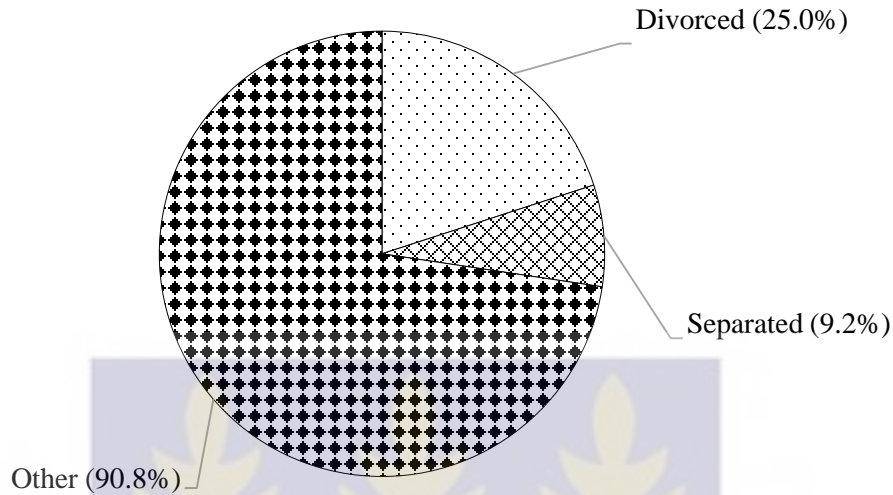
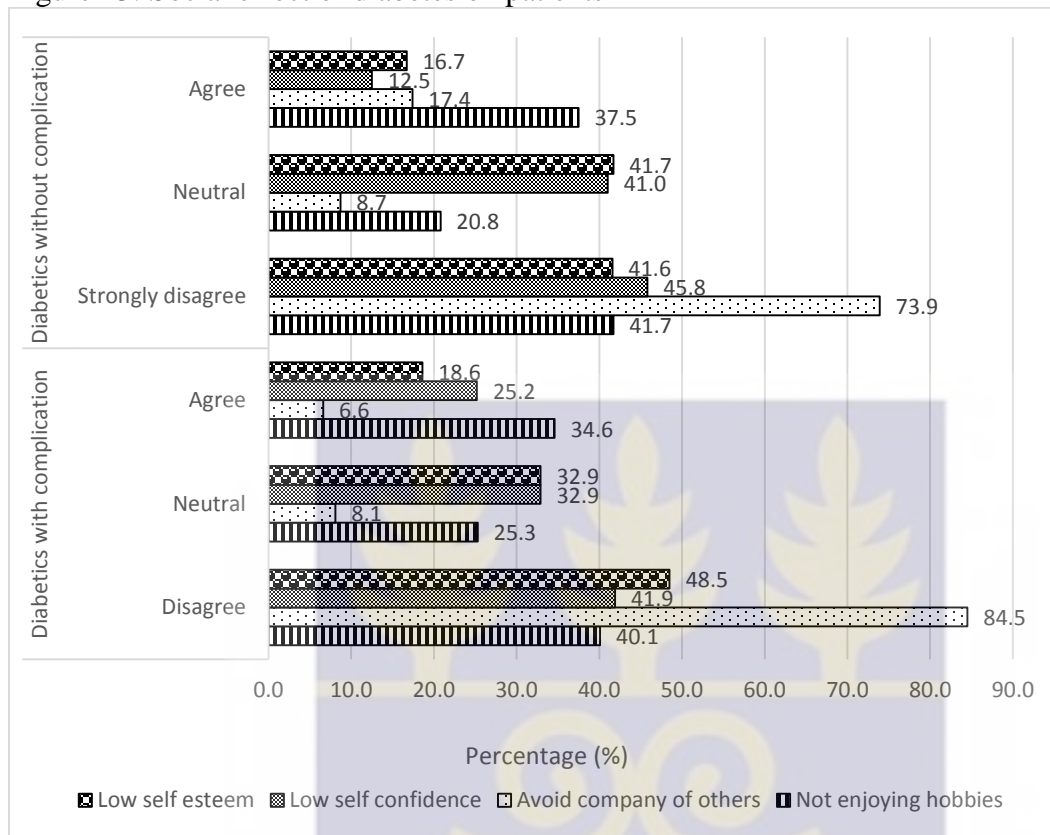


Figure 13 further presents the social effects of the type-2 diabetes disease in terms of self-esteem, self-confidence, social interaction and ability to pursue hobbies. Most of the complicated diabetics (84.5%) (n=218) and non-complicated diabetics (73.9%) (n=17) strongly disagreed that they avoid company of others. While all diabetics without complications did not agree they have low self-esteem and self-confidence, 3.1% (n=8) and 5% (n=13) of patients suffering complications strongly agreed they have low self-esteem and self-confidence respectively. Furthermore, about 8% (n=2) of diabetics without complications strongly agreed they are unable to enjoy hobbies compared to about 10% (n=25) of patients with complications.

Figure 13: Social effect of diabetes on patients



4.8.3 Work related effect

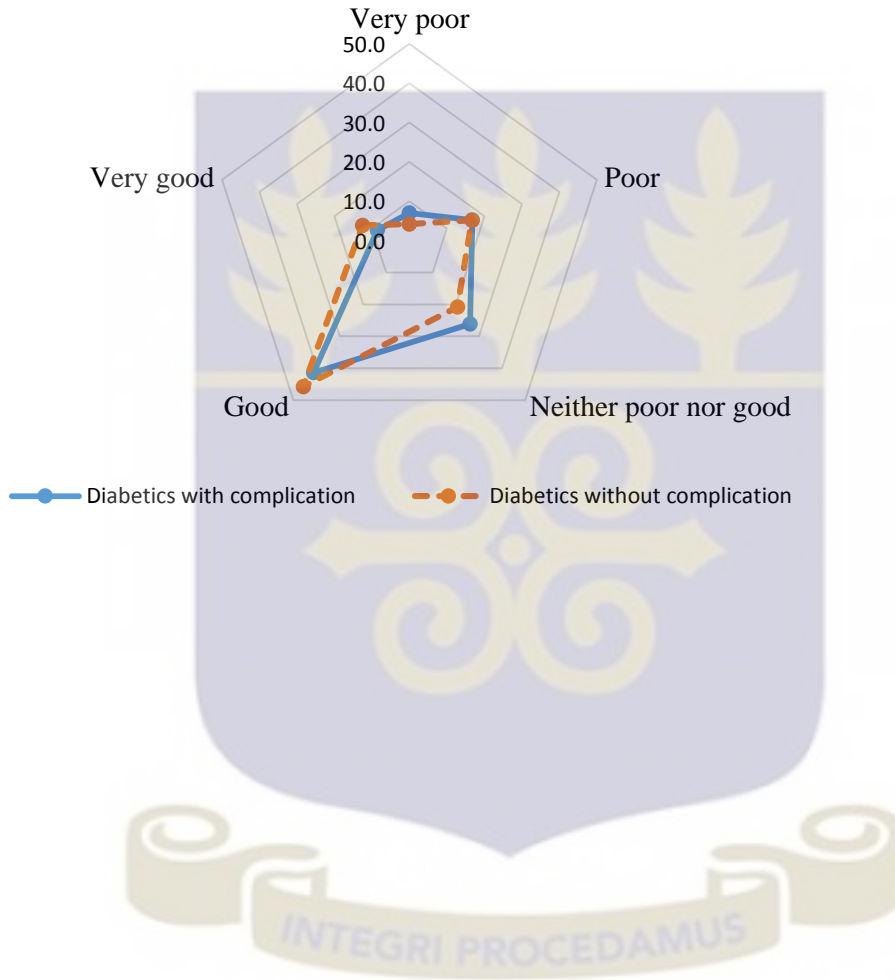
About 45% (n=116) of diabetes patients with complications had to retire from work because of the condition of their illness compared to about one-third of those without complications.

4.8.4 Quality of life assessment

As shown in Figure 14, many diabetics with complications (41.4%) (n=107) and those without complications (45.8%) (n=11) assessed their quality of life as good. Thus, there was no significant difference in the quality of life of diabetics with complications and those without complications. Furthermore, about 24% (n=62) of complicated diabetics and 21% (n=5) of non-complicate diabetics assessed their quality of life as poor whereas 25.7% (n=72) of all study

diabetics rated their quality of life as neither poor nor good. Type-2 diabetes patients rated their overall quality of life as good. The weighted average score of quality of life for all study patients was 3.3 indicating reasonably good quality of life.

Figure 14: Quality of life assessment of type-2 diabetics



CHAPTER FIVE

DISCUSSION

This chapter presents the discussions of the study. The outline is based on the objectives of the research. It includes summary and discussion of the key findings of the study and relate it to published literature on cost burden of type-2 diabetes mellitus treatment as well as physical and psychological pain associated with the disease.

In summary, over 91% of patients are suffering from complications, in some cases multiple complications. The mean age of diabetes patients is above 55 years which indicates that type-2 diabetes is more prevalent among the elderly, similar to a finding by Xiaohui Zhuo *et al.* (2014). The disease could also be more prevalent among females since they constitute almost 80% of this study patients. Employment status did not vary between diabetics with complications and those without complications. Employed diabetics averagely spend GHS179.62 (95% CI: 0-615.57) on diabetes healthcare compared to unemployed diabetics who spend averagely GHS138.40 (95% CI: 0-296.68). Additionally, most of the type-2 diabetes study patients who have complications (55%) are unemployed due to their condition compared to those without complications (25%). The mean treatment cost of diabetics with complication was GHS175.61 (95% CI: 0-429.55).

The overall estimated total cost of diabetes treatment for diabetics with complications and those without complication together is GHS47,853.54 (US\$12,270.14). The mean and median cost for patients with complications are GHS184.45 (95% CI: 0-521.58) and GHS128.89 respectively. The estimated direct cost constitutes the bulk of the total treatment cost profile (94.3%) compared to total indirect cost (5.7%). Higher percentage of diabetics with complication (20.2%)

suffer very severe physical pains than complicated diabetics (16.7%). More diabetics without complications (83.3%) compared to those with complications (59.7%) agree they have changed diet due to their diabetes illness. Adherence to dietary plan is very germane to type-2 diabetes treatment especially those suffering complications. Most observed complications cases can be attributed to diabetics' non-adherence to dietary plan and relevant health education aimed at curbing complications and co-infections. About 44% of patients had their marriages affected by the diabetes conditions one way or the other. Type-2 diabetes affects self-esteem and self-confidence of patient with complications than those without complications.

5.1 Direct Treatment Cost Of Type-2 Diabetes Mellitus.

The direct non-medical cost contributes an inappreciable proportion (10.7%) to the total direct cost profile compared to direct medical cost (89.3%). This is contrary to finding by Chatterjee (2011) which reported relatively substantial contribution of 40% direct non-medical cost to total direct cost profile among diabetes patients.

The total direct treatment cost estimated in this study for type-2 diabetics suffering complications and comorbidities was GHS42,186.70 (US\$10817.10) whereas that for patients without complications was GHS2,930.84 (US\$751.50). The mean costs are GHS163.51 (95% CI: 0-508.97) and GHS122.12 (95% CI: 43.77-200.47) for complicated diabetics and non-complicated diabetics respectively. This shows that diabetics with complications have higher cost burden compare to those without complications. Furthermore, the median for diabetics suffering complication was GHS110.51 whilst that of patients without complication was GHS103.31. However, it is worth noting that the average cost of treating diabetic complication per month (GHS163.51) far outweighs annual cost of averting complications through glucometer ownership and weekly glucose monitoring (GHS200.00). This study finds that direct cost (94.3%) constitute

a very significant portion of the total treatment cost profile in contrast to indirect cost (5.7%). The high percentage share of direct cost estimated in this study confirms findings by American Diabetes Association (2013), where the direct cost of diabetic healthcare formed about 71.8% of the total cost of diabetic healthcare. Likewise, results from a study conducted by Kirigia *et al.* (2009) showed that the direct cost of diabetic healthcare (56%) formed a greater portion of the total cost of diabetic healthcare. However, findings of this study is in sharp contrast to study results obtained by Barceló *et al* (2003) which concluded that the direct cost of diabetic healthcare constituted a lesser proportion (16%) of the total cost of diabetic healthcare. The contrast could possibly be attributed to contextual differences.

This study's estimates of high percentage share of direct cost over total treatment cost can largely be ascribed to the influence of cost of medications prescribed for treatment of diabetics and its related complications/comorbidities. Medication cost alone accounts for 67.2% of the total cost profile. The same finding was observed by the American Diabetes Association (2013) which found that the largest proportion of the direct cost of diabetic healthcare was attributable to the percentage share of medicine cost (18%). Similarly, this study's result is corroborated by the study findings of Barceló *et al.* (2003), which also concluded that medications cost formed the highest proportion of the direct cost of diabetic healthcare (41%). Notwithstanding the influence of medicine cost which resulted in high percentage share of direct cost over total treatment cost profile, the real effect of cost of medications is possibly under estimated. This is due to the fact that most of the medications used in diabetes treatment were covered under the National Health Insurance Scheme (NHIS) (NHIS medication Tariffs, 2012) and majority of the study patients are NHIS subscribers.

Type-2 diabetics unlike type-1 diabetics are strictly supposed to be non-insulin dependent. Measures used to manage the disease include oral medication, regular exercise and adherence to dietary plan. However, more than half of the studied diabetics (51.2%) are insulin dependent. Reasons attributed to patients reliance on insulin are: (1) study hospital's standard of practice to use insulin to normalise severely high glucose levels of type-2 diabetics; (2) patients' resistance to medication over time (e.g. the average years patients had been diagnosed with type-2 diabetes in this study was 8years); and (3) to supplement patients medication in order to keep glucose at normal levels and prevent complication risk. This study's findings partially disproves Beran *et al.* (2008) study report that medication, insulin etc. needed for management of the disease are frequently in short supply in many countries and where they are available, often they are unaffordable due to lack of subsidies. This study finds that though there is constant supply of insulin, the NHIS did not cover the entire cost and thus patients are made to pay about 20% of high price medicinal products like insulin.

5.2 Indirect Treatment Cost of Type-2 Diabetes Mellitus

The cost burden of managing type-2 diabetes mellitus goes beyond direct spending on medical products and commodities. It extends to other indirect cost elements. This is expressed as loss of productivity resulting from absenteeism and patient's inability to engage in productive activities. According to WHO (2013), due to the chronic and complex nature of the disease, diabetic patients may either be unable to work or effectively work as they could prior to the onset of the disease. This study's findings reveals that diabetics with complications and those without complications lost over 70% of the estimated productive work time due to work absenteeism.

WHO (2013) further reported indirect cost estimates for type-2 diabetes management in many countries may be as great as or even greater than the direct health care cost. In this study, due to cultural factors which inhibit people from revealing correct information about their income, Ghana's minimum wage as of June 2016 (GHS8.00) is used to estimate indirect cost of all employed diabetics. This approach may have biased the cost estimation and thus confirms WHO's stance. Also, this was evident in the study results of Barceló *et al.* (2003) in which the percentage share of total indirect cost constituted about 82% of the total cost of diabetic care.

Furthermore, a survey conducted by Kapur (2007) on the cost of diabetes mellitus in India reported that the indirect cost burden in the management of diabetes mellitus disease formed more than half of the total healthcare expenditure. However in contrast to the finding of Kapur's (2007), indirect cost estimated in this study constitute less than 10% of the total treatment cost. Again, this findings is in sharp contrast with study results of Kirigia *et al.* (2009), who in a standard cost-of-illness study in the WHO African region reported that the indirect cost burden of type-2 diabetes disease management was significantly not different from the direct cost resulting from the disease (i.e. direct cost was 57% and indirect cost was 43%). Nonetheless, consistent with this study is a research by Chatterjee *et al.* (2011) which reported that the indirect cost of diabetic health care formed less than half of the total cost of diabetic health care. Likewise, American Diabetes Association (2013) reported that indirect cost of diabetes mellitus disease management constituted less than 30% of the total health care expenditure.

According to American Diabetes Association (2013) report which documented the extent of economic loss from absenteeism and low productivity due to diabetes care, diabetic management leads to more than 7% increase in absenteeism. This study results reinforces the findings, given that the valued waiting time at the hospital alone constitute 19% of the total indirect cost.

Furthermore, valued productive work hours lost due to absenteeism accounted for over 78 % of total indirect cost and 5.6% of total treatment cost. Similar to this findings, study done by Kapur (2007) showed that productivity losses accounted for the highest proportion (71.8%) of the indirect cost. However, inconsistent with findings by Kirigia *et al.* (2009) which reported that the total indirect cost constituted about 43% of the total cost of diabetic health care, this study's estimated indirect cost constitutes 5,7% of total treatment cost.

5.3 Intangible Cost Associated With Type-2 Diabetes Mellitus

The burden associated with managing type-2 diabetes further extends to physical and psychological pain, stress and anxiety which adversely affect the quality of life of diabetics. Findings of this study shows that a substantial number (45%) of type-2 diabetics who used insulin often felt discomfort and stressed during its administration. This corroborates WHO (2013) report which observed that the management of the disease especially by insulin injection may be inconvenient, time-consuming and a potential source of psychological stress.

Kirigia *et al.* (2009) in a study emphasized the point that intangible burden suffered due to diabetes contributes significantly to the overall cost burden. Majority of patients suffer various degrees of depression and physical pains ranging from moderate to very severe. Similarly, a study by Anderson *et al* (2001) showed that people with diabetes had twice the odds of depression compared to those without depression. Diabetics must be encouraged to regularly engage in physical activities and hobbies in order to prevent stress and depression associated with the diabetes mellitus disease. Trovato *et al.* (2006) reported an association between diabetes and psychological stress. This is, similar to results of this study in which diabetics with complication (20.2%) suffer very severe physical pains than non-complicated diabetics (16.7%).

Similarly, Donald *et al.* (2012) examined the cost of diabetes mellitus and concluded that about 42% of diabetics lived with pain and discomfort and 34% were depressed and had anxiety tendencies. The lower levels of physical pain among diabetics can be attributed to their constant adherence to treatment schedule as a result of NHIS membership. Most of the medication that relieved them of physical pain is covered under the NHIS.

Donald *et al.* (2012) stated that less than a third of study patients had problems with mobility and ability to undertake usual activities with ease. This is similar to findings of this study in which even lower proportion of patient report of inability to enjoy hobbies. About 45% of diabetes patients with complications have to retire from work because of the condition of their illness compared to about one-third of those without complications. The fasting blood sugar level of majority of study diabetics is above the normal level of 6.1mmol/dL, a situation which is a risk factor for complications and comorbidities. Quality of life assessment of patients indicate reasonably good quality of life – i.e. weighted average score (from 1-5) of quality of life for all study patients was 3.3. WHO (2015) reported that pain, anxiety, discrimination at workplace, difficult in obtaining jobs was mainly due to complications, stigmatization and other factors which decrease quality of life. In this study, diabetics with complications have slightly lower quality of life (weighted mean score of 3.3) compared to patients without complications (weighted mean score of 3.5).

5.4 Total Treatment Cost of Type-2 Diabetes Mellitus by Socioeconomic Status

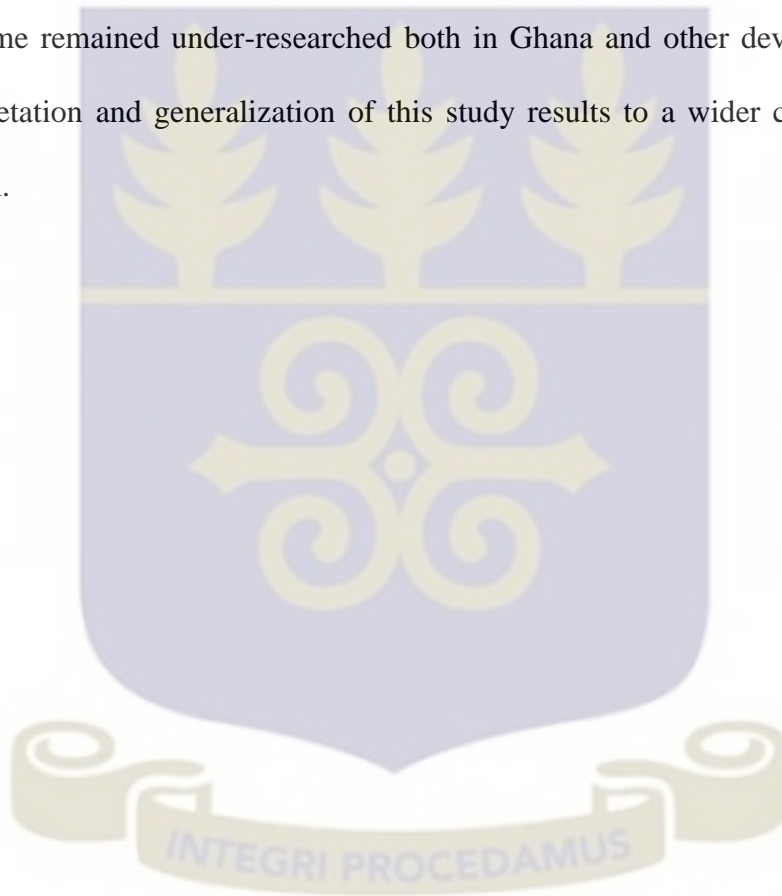
Findings of this study suggest that diabetics in the fourth socioeconomic group spend on average greater amount of money on treatment. On the other hand, the total contribution of those in the lowest group constitute the highest of the total treatment cost. Diabetics with complications spent

on average GHS151.93 (95% CI: 0-318.78) on treatment compared to non-complicated diabetics who spent GHS91.01. This can be attributed to the fact that those in the fourth socioeconomic group suffer less complications because they have the means to better manage the disease e.g. better dietary arrangement etc. This corroborates studies by Engum *et al.* (2005) and Knol *et al.* (2007) which attributed higher risk to people with lower socioeconomic status, also known as inverse social gradients.

Further analysis is done on the mode of payment for diabetes health care by patients. About 2% of patients paid directly out-of-pocket (OOP) whilst less than one percent (0.4%) relied on private insurance. Co-payment i.e. shared health care cost payment by patient and National Health Insurance Scheme (NHIS) was the most dominant payment mechanism (77.1%). Out of the number who rely on co-payment, health care cost of about two-third diabetics is jointly borne by patients and NHIS, while the other one-third is by NHIS and patients' relatives. This situation prevails because even though almost all study patients have subscribed to NHIS, the insurance did not cover all health care expenses incurred by diabetics. Those who can not co-fund solely rely on the NHIS (20.4%) which has implications for comorbidities and complications.

Furthermore, cost of health care played is a major factor of health seeking behaviour of type-2 diabetics. Significant number of patients (60%) skip diabetes treatment because of costs. Other reasons why diabetics skip treatment include waiting time at hospital. Further analysis done on percentage of total income patients without insurance spend on their diabetes healthcare suggest that more than a quarter of patients spent over 75% of their income on diabetes treatment. Thus, diabetics' subscription to mutual and national health insurance schemes will greatly ensure financial risk protection and avoid catastrophic expenses associated with type-2 diabetes mellitus.

The main limitation of this study is the inability to get a fair mix of complicated and non-complicated diabetic cases, which could have improved the rigor of the study. Furthermore, productivity losses due to presenteeism, caregiver costs and costs of premature mortality have not been considered in the estimation of indirect cost. As a result, the indirect cost estimates reported herein are likely to be under-estimates. This notwithstanding, the study has made valuable contribution to the better understanding of economic burden of type-2 diabetics which has for a long time remained under-researched both in Ghana and other developing countries. However, interpretation and generalization of this study results to a wider context need to be done with caution.



CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

This chapter summarizes the significance and implication of the study and makes recommendations which aims to inform policies and programmes targeted at improving the current management of the diabetes mellitus disease in order to mitigate the economic burden associated with the disease.

6.1 Conclusion

Generally type-2 diabetes is predominant among the elderly and the economic burden it poses is enormous. While most of the elderly have retired because of their diabetes condition, many more have retired because of age. The effect of this situation on households and the country at large could be dire and thus must not be downplayed. The chronic nature of the disease makes absenteeism from work imminent especially at complicated stage. However, with a well decentralized diabetes healthcare services to lower levels facilities (e.g. health centres, district hospital) and vigorous public health interventions (e.g. health promotion and; behaviour change communication and education), complications associated with the disease could be minimized substantially as well as lost productive hours.

The complexity of the disease require constant and regular treatment regime. Meanwhile the high cost burden associated with diabetes treatment especially for those with complications could have negative implications for health seeking behaviour of patients. Patients who pay out-of-pocket or co-pay for healthcare services mainly bear the brunt of this situation as they sometimes have to skip treatment due to cost.

The study's analysis of estimated total treatment cost and related intangible burden of type-2 diabetes mellitus suggest that the real and economic burden the disease pose on individuals and

larger economy cannot be underestimated. The burden can largely be lessened through pragmatic health services and public health interventions.

6.2 Recommendation

The study makes the following recommendation:

Ghana Health Service and stakeholders

1. Health facilities should encourage patients to enroll into the National Health Insurance Scheme. This would help eliminate or substantially reduce health expenditure associated with diabetes management.
2. National Health Insurance Authority should cover the full cost of diabetes medication including insulin. This would reduce the burden of direct medical cost on patients in instances where patients have to top-up payment regularly at every OPD visit.

Individual diabetics

1. Patients should be encouraged to adhere to their dietary plan, undertake regular physical activities and exercises. This would increase insulin sensitivity in order for the cells to better be able to utilize insulin and keep glucose at normal level thereby improving their health and thus prevent complications and its associated costs.

Further research

1. Studies should be undertaken to estimate the household cost of diabetics.
2. Studies should be undertaken to estimate the economic burden of type 2 diabetes – expanding indirect cost scope to include productivity losses due to presenteeism and caregiver costs.

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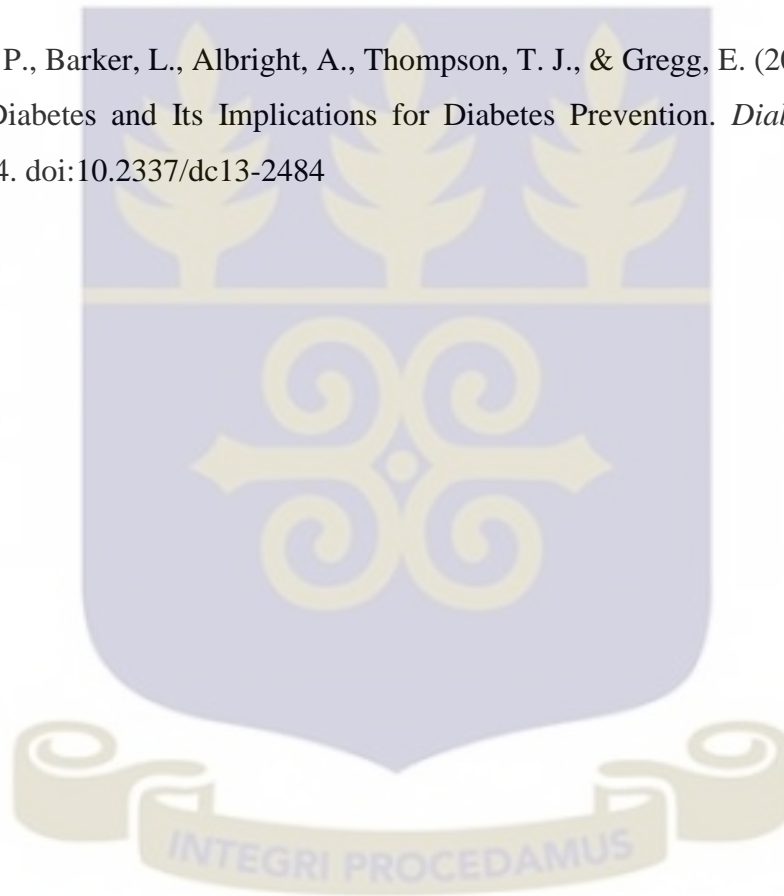
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APPENDICES

Appendix I: Participant Information Leaflet

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

Title of Research: Economic burden of type-2 diabetes mellitus: A case study of patients attending Eastern Regional Hospital Outpatient Clinic.

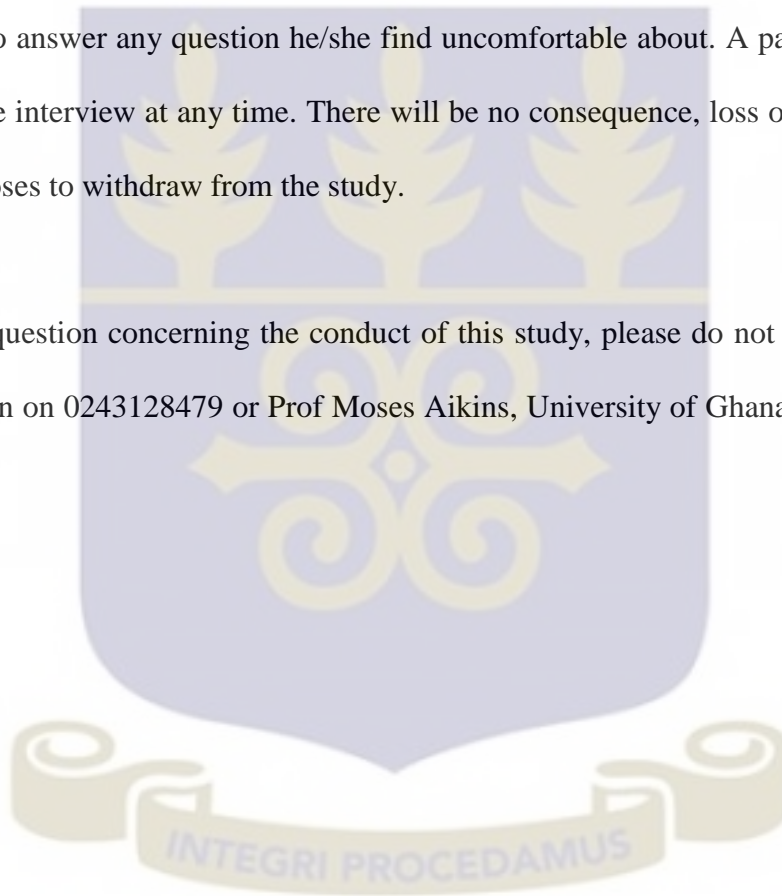
This study is being conducted by Mr. Samuel Kotei Amon, a student at the University of Ghana, School of Public Health, as part of the requirement in pursuing an MPH programme.

This study seeks to bring to light the actual cost borne by diabetes patients in the management of the disease. A structured closed-ended questionnaire covering all aspects of the objectives of the study will be used for data collection. For the participants who are on the NHIS the amount paid for consultation, medications and laboratory investigations will be sought from the hospital records. In total I expect to interview 270 participants for this study. This number will comprise of both diabetics with complications and those without complications. The interview will take some of your time and might be an inconvenience. It might take about 30 minutes to complete the questionnaire.

Participants will gain a better insight into the cost of managing the disease, the control measures to take and ways of improving the quality of the management of the disease. It will also inform policy makers on better and more effective ways of developing safety interventions and preventive educational campaigns in addition to the body of knowledge on cost of diabetes management 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. Diabetic 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 not to answer any question he/she find uncomfortable about. 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 Mr. Samuel Amon on 0243128479 or Prof Moses Aikins, University of Ghana, School of Public Health.



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**Topic: Economic burden of type-2 diabetes mellitus: a case study of patients attending eastern regional hospital outpatient clinic**

Dear respondent,

This is a research carried out on diabetes in the New Juabeng Municipal of Eastern Region. I will therefore like to take a few minutes of your precious time to answer these questions. You are assured that the answers you give will be strictly confidential and your name will not be mentioned in my response report. Thank you.

| Qn No. | Questions | Response |
|-------------------------|---|--------------|
| Respondent ID: _ _ _ _ | | |
| Section 1 | Socio-demographic information | |
| 1 | What is your sex 1. Male 2. Female | _ |
| 2 | What is your age in years (i.e. age at last birthday)? | _ _ _ years |
| 3 | What is the highest level of school you attended? 1. No education 2. Primary 3. Middle 4. JSS/JHS 5. Secondary/Vocational 6. SSS/SHS 7. Higher | _ |
| 4 | What is your current marital status? 1. Married/living together 2. Divorced/ Separated 3. Widowed 4. Never married | _ |
| 5 | What is your employment status? 1. Unemployed 2. Employed <i>If unemployed, go to Qn 7</i> | _ |
| 6 | If employed, what is your occupation, that is, what kind of work do you mainly do? | |

| Qn No. | Questions | Response |
|------------------|--|----------------------|
| 12 | Does any member of this household own: | |
| | a) Bicycle 1. Yes 2. No | _ _ |
| | b) Motorcycle/scooter 1. Yes 2. No | _ _ |
| | c) Wrist watch 1. Yes 2. No | _ _ |
| | d) Animal-drawn cart 1. Yes 2. No | _ _ |
| | e) Car/truck 1. Yes 2. No | _ _ |
| | f) Boat with motor 1. Yes 2. No | _ _ |
| | g) Boat without motor 1. Yes 2. No | _ _ |
| 13 | Is the cooking <i>usually</i> done in the house, in a separate building, or outdoors? 1. In the house in a separate room 2. In a separate building 3. Outdoors 4. Other (please specify) | _ _ |
| 14 | What type of fuel does your household <i>mainly</i> use for cooking? 01. Electricity 02. LPG 03. Natural gas 04. Biogas 05. Kerosene 06. Coal, lignite 07. Charcoal 08. Wood 09. Straw/shrubs/grass 10. Agricultural crop 11. Animal dung 12. No food cooked in household 13. Other (specify) | _ _ |
| Section 2 | Health status and treatment information | |
| 15 | What is your current fasting blood glucose/sugar level? | _ _ . _ _ mmol/L |
| 16 | Since how long have you been diagnosed as diabetic? | _ _ |
| 17 | Have you been diagnosed with any of the following co-morbidities/complication due to diabetes? | |
| | (a) Hypertension 1. Yes 2. No | _ _ |

| Qn No. | Questions | Response |
|--------|---|--|
| | (b) Dyslipidemia (High cholesterol) 1. Yes 2. No | <input type="checkbox"/> |
| | (e) Retinopathy (Eye damage) 1. Yes 2. No | <input type="checkbox"/> |
| | (f) Neuropathy (Nerve disease) 1. Yes 2. No | <input type="checkbox"/> |
| | (g) Nephropathy (Kidney damage) 1. Yes 2. No | <input type="checkbox"/> |
| | (h) Foot Ulcer 1. Yes 2. No | <input type="checkbox"/> |
| | (i) Skin conditions 1. Yes 2. No | <input type="checkbox"/> |
| | (j) Hearing impairment 1. Yes 2. No | <input type="checkbox"/> |
| | (k) Alzheimer's disease (Brain disorders) 1. Yes 2. No | <input type="checkbox"/> |
| | (l) Depression 1. Yes 2. No | <input type="checkbox"/> |
| | (m) Other (please specify) | |
| 18 | What condition did you receive treatment for today? 01. Hypertension 02. Eye 03. Nerve 04. Kidney 05. High cholesterol 06. Foot Ulcer 07. Skin conditions 08. Hearing impairment 09. Depression 10. Other (please specify) | <input type="checkbox"/> |
| 19 | Do you skip diabetes treatment because of: a) Cost 1. Yes 2. No b) Work 1. Yes 2. No c) Distance to hospital 1. Yes 2. No d) Nobody to accompany you to hospital 1. Yes 2. No e) Lengthy time spent at hospital 1. Yes 2. No f) Other, please specify _____ | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| 20 | Who pays for your diabetes treatment? 1. Self 2. Spouse 3. Parent | |

| Qn No. | Questions | Response |
|------------------|---|----------------------|
| | 4. Brother/sister 5. Son / Daughter 6. Employer 7. National Health Insurance 8. Private Health insurance 9. Other (please specify) | <input type="text"/> |
| Section 3 | Direct cost information | |
| 21 | <i>Direct medical cost information</i> How much money (GHS) did you spend for: | |
| | (a) Consultation? | <input type="text"/> |
| | (b) Lab tests? | <input type="text"/> |
| | (c) Treatment? | <input type="text"/> |
| | (d) Medicines: Which drugs were given for diabetes and other co-morbidities/complications? | |
| | (i) Dose: _____ | <input type="text"/> |
| | (ii) Dose: _____ | <input type="text"/> |
| | (iii) Dose: _____ | <input type="text"/> |
| | (iv) Dose: _____ | <input type="text"/> |
| | (v) Dose: _____ | <input type="text"/> |
| (vi) Dose: _____ | <input type="text"/> | |
| | <i>Total medicine cost</i> | <input type="text"/> |
| 22 | <i>Direct non-medical cost information</i> How much money did you spend for? (GHS) | |
| | (a) travel cost | <input type="text"/> |
| | (b) food cost | <input type="text"/> |

| Qn No. | Questions | Response |
|--------|---|--------------------------|
| 32 | If retired, was the retirement as a result of the diabetes? 1. Yes 2. No 3. Not applicable | <input type="checkbox"/> |
| 33 | How often do you feel uncomfortable when you administer insulin injection? 1. Always 2. Very Often 3. Quite often 4. Seldom 5. Never | <input type="checkbox"/> |
| 34 | How often do you feel stressed out when you have to administer insulin injection? 1. Always 2. Very Often 3. Quite often 4. Seldom 5. Never | <input type="checkbox"/> |
| 35 | If married, how has diabetes affected your marriage? 1. No effect 2. Divorced 3. Separated 4. Other (please specify) | <input type="checkbox"/> |
| 36 | I am not able to enjoy my hobbies as I did prior to the diagnosis of the disease? 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree | <input type="checkbox"/> |
| 37 | I have sleepless nights because of diabetes condition? 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree | <input type="checkbox"/> |
| 38 | I have low self-confidence because of diabetes condition 1. Strongly disagree 2. Disagree 3. Neutral | <input type="checkbox"/> |

| Qn No. | Questions | Response | | | | | | | | | | |
|-----------|---|--------------------------|------|-----------------------|------|-----------|---|---|---|---|---|--------------------------|
| | 4. Agree 5. Strongly agree | <input type="checkbox"/> | | | | | | | | | | |
| 39 | I have low self-esteem because of diabetes condition 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree | <input type="checkbox"/> | | | | | | | | | | |
| 40 | I avoid company of others because of my diabetes condition 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree | <input type="checkbox"/> | | | | | | | | | | |
| 41 | I easily get fatigued because of my diabetes condition 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree | <input type="checkbox"/> | | | | | | | | | | |
| 42 | I have to change diet because of diabetes 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree | <input type="checkbox"/> | | | | | | | | | | |
| 43 | I easily get irritated because of my diabetes condition 1. Strongly disagree 2. Disagree 3. Neutral 4. Agree 5. Strongly agree | <input type="checkbox"/> | | | | | | | | | | |
| 44 | On a scale of one to five, how would you rate your quality of life? <table border="1" style="width: 100%; text-align: center;"> <tr> <td>Very poor</td> <td>Poor</td> <td>Neither poor nor good</td> <td>Good</td> <td>Very good</td> </tr> <tr> <td>1</td> <td>2</td> <td>3</td> <td>4</td> <td>5</td> </tr> </table> | Very poor | Poor | Neither poor nor good | Good | Very good | 1 | 2 | 3 | 4 | 5 | <input type="checkbox"/> |
| Very poor | Poor | Neither poor nor good | Good | Very good | | | | | | | | |
| 1 | 2 | 3 | 4 | 5 | | | | | | | | |

THANK YOU FOR YOUR TIME.

Appendix IV: Ethical Approval Certificate

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

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



My Ref. GHS/RDD/ERC/Admin/App/16/02
Your Ref. No.

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

3rd February, 2016

Samuel Kotei Amon
University of Ghana
School of Public Health
Legon, Accra

ETHICS APPROVAL - ID NO: GHS-ERC: 13/12/15

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

“Economic Burden of Type-2 Diabetes Mellitus: A Case Study of Patients Attending Eastern Regional Outpatient Clinic”

This approval requires that you submit yearly review of the protocol to the Committee and a final full review to the Ethics Review Committee (ERC) on completion of the study. The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Please note that any modification without ERC approval is rendered invalid.

You are also required to report all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.

You are requested to submit a final report on the study to assure the ERC that the project was implemented as per approved protocol. You are also to inform the ERC and your sponsor before any publication of the research findings.

Please note that this approval is given for a period of 12 months, beginning 3rd February, 2016 to 2nd February, 2017. However, you are required to request for renewal of your study if it lasts for more than 12 months.

Please always 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