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ASSESSMENT OF THE ECONOMIC BURDEN OF DIABETES MANAGEMENT TO HOUSEHOLDS IN DENKYEMBOUR DISTRICT, EASTERN REGION, GHANA

BY

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DECLARATION

STUDENT'S DECLARATION

I, ADAM JOSEPH, hereby declare that except for the reference of the other people's work which I have duly acknowledged, this long essay consist of my own work produced from the research I undertook undersupervision, and that no part has been presented for degree elsewhere.

Signature: ……. **Date: ……..**

Name of student: ……..

SUPERVISOR'S DECLARATION

I hereby declare that, the preparation and presentation of this long essay is being supervised in accordance with the guidelines on supervision of long essay laid down by the University of Ghana, Legon

Signature: ……..…… **Date: ……..……**

Name of the supervisor: ……..…….

DEDICATION

I dedicate this dissertation to my family who supported me in various ways throughout my education to date.

ACKNOWLEDGEMENT

I am very grateful to God Almighty for giving me strength, wisdom and knowledge to be able to write this dissertation.

I thank my academic supervisor, Dr. Patricia Akweongo for her direction, guidance, encouragement, and inputs towards this dissertation.

I wish to register my sincere gratitude to the School of Public Health, University of Ghana and the entire staff for their support in diverse ways that helped me in writing this dissertation.

Finally, my appreciation goes to my family for their support.

ABSTRACT

Introduction: The cost of diabetes care continues to rise with its associated toil on patients and their households due to its chronicity and complications which need continuous management. This puts serious economic burden to households, nations and the world at large; and therefore cannot be underestimated. Evidence based knowledge in this subject, is therefore of essence to help inform policies and programmes for diabetes management and cost containment.

Objective: The objective of this study was to assess the economic burden of diabetes management to households in Denkyembour District, Eastern Region.

Method: Descriptive cross sectional study design was used to assess the economic burden of diabetes to households in Denkyembour District, Eastern Region. The study employed quantitative approach for the data collection. Systematic sampling technique was used to select 224 diabetes patients from the sampling frame of 986 diabetes patients. Closed ended questionnaires were used to collect the data. The data was entered into Microsoft excel and STATA Version 15 for analysis. The data was then summarized into frequencies, means, proportions, standard deviation.

Ethical Approval: Ethical approval was sought from Ghana Health Service Ethical Review Committee; and approved.

Results: The mean age of the respondents was 56 years with the modal age of 45 – 54 years. One hundred and thirty five (135) of the 224 respondents were employed. The average monthly income of the earning diabetics was GHS 377.76 (USD 80.55). The overall total cost estimate for diabetes treatment was GHS 49,175.17 (USD 10,485.11) with the total mean cost of GHC 219.53 (USD 46.81). The estimated direct cost constitutes the bulk of the total treatment cost

with a cost profile of 82.2% while indirect cost constituting 17.8%. In the ascending order scale of one (1) to five (5), the degree of physical pain and psychological pain were rated 2.15 and 2.73 respectively.

Conclusion: The findings of this study showed that the estimated total treatment cost and intangible cost of diabetes pose considerable economic burden as patients spend close to 60% of their monthly earnings on diabetes management. This reduces their household income significantly.

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LIST OF ABBREVATIONS

ADA: American Diabetes Association

ANOVA: One way Analysis of Variance

COI: Cost of Illness

DKA: Diabetic Keto Acidosis

DM: Diabetes Mellitus

FPG: Fasting Plasma Glucose

GAD: Glutamic Acid Decarboxylase

GCD: Ghana Consolidated Diamond

GDP: Gross Domestic Products

GHS: Ghana Cedi

2HR: 2 Hours

IADPSG: International Association of Diabetes and Pregnancy Study Group

ICU: Intensive Care Unit

IDF: International Diabetes Federation

IV: Intravenous

LMIC: Low and Middle Income Countries

Mmol/L: Millimol per Liter

NHIS: National Health Insurance Scheme

NONDM: Nondiabetic Mellitus

OPD: Outpatient Department

POLO: Polytrauma Outcome Chart (POLO-Chart)

RPG: Random Plasma Glucose

SD: Standard Deviation

SES: Socioeconomic Status

St.: Saint

T1DM: Type One Diabetes Mellitus

UNICEF: United Nations International Child Emergency Funds

USA: United State of America

USD: United State Dollar

WBFPG: Whole Blood Fasting Plasma Glucose

WHO: World Health Organisation

WIFA: Women In Fertility Age

DEFINITION OF OPERATIONAL TERMS

Burden: The undue financial pressure, physical pain and psychosocial pain on patients (diabetics), households and health systems due to illness (diabetes)

Household: Group of people who live together and interdepend on one another economically, physically and psychosocially

Direct cost: The cost or expenditure directly incurred by patients, households, society and health systems on medications, investigations, hospitalization, procedures and transportation to hospital in order to treat diabetes

Indirect cost: This refers to the productivity losses made by the patients, households and health systems due to productive time lost on travelling to hospital for treatment, or on hospitalization or on disability caused by diabetes

Intangible cost: This is non-monetary cost that is usually related to physical pain, psychological pain and social effects which negatively affect the quality of life of the diabetics. It is descriptively measured using the Likert scale to rate the extent of the cost burden

Composite intangible cost: This is the summation of intangible cost dimensions (ratings) under every cost variable (domain) such as physical pain, psychological pain and social effect suffered by diabetics, and multiplying the score with the number of questions. The total score could be reclassified/divided into 3 categories namely low intangible cost (lower range limit of the score), moderate intangible cost (average range limit of the score) and high intangible cost (upper range limit of the score) to give a clearer picture of the level of the intangible cost

Valued productive time lost: Productive time lost that is translated into monetary terms/value

CHAPTER ONE

1.0. INTRODUCTION

1.1. Background

Diabetes is a chronic metabolic disorder which is characterized with high blood glucose level. It comes as a result of reduced or absence of insulin secretion from the pancreas and/or reduced effectiveness of insulin in the tissues (insulin resistance). There are four types of DM namely type1, type2, gestational and diabetes with other specific causes (diabetes due to genetic defect of the β-cells, endocrine diseases, exocrine diseases, chemical toxins and pancreatic trauma). It is characterised with polyuria, polydipsia, and hyperglycaemia among others. Individuals with DM are at higher risk of developing debilitated health problems compared to those without it as consistent high blood glucose levels can seriously lead to diseases that could affect the heart and blood vessels, eyes, kidneys and nerves (International Diabetes Federation, 2015)

International Diabetes Federation in their 2015 findings, reported that diabetes is a leading cause of renal failure, eye problems or loss of vision,cardiovascular disease, and lower limb amputations(International Diabetes Federation, 2015). It is a complex disease that needs continuous management/treatment with medications, investigations, dietary and self-management in order to prevent complications and death. DM is a global challenge now as it is getting to the pandemic level. For all age groups, the estimated direct annual cost of DM to the world is higher than US$ 827 billion as the total global health care spending on diabetes more than tripled over the period 2003 to 2013 (World Hralth Organisation, 2016.). Sub Saharan Africa is not an exception to this menace of diabetes and cost of its management. Thus Hall et al in their 2011 publication reported that the total annual cost of DM management in Africa

wasUS$67.03 billion, or US$8836 per diabetic patient (Victoria Hall; Reimar W. Thomsen; Ole Henriksen and Lohse, 2011). In Ghana, the Diabetes Association estimated that there are about 4 million diabetics in Ghana of the 28 million population (Kwawukume, 2017).

Despite the fact that it is very expensive to manage diabetes, the clients with the condition are expected to visit hospital for care either monthly or twice monthly or even within a week depending upon his/her health status. This puts so much financial burden on the clients and their households. The direct, indirect and intangible costs are the main components of the cost implication of diabetes management on households and clients. Some of the services captured under direct cost include oral medications, insulin, diagnostic investigations, syringes and needles, glucometers and blood lancets, consultation, hospitalization and transportation while lost to productivity as a result of lost time, permanent disability, mortality/morbidity make up the indirect cost. Another burden is the intangible cost, which could lead to productivity losses due to psychological stress, pain and anxiety. Households find it very difficulty coping with the cost of services associated with diabetes. A study conducted in four cocoa clinics in Ghana (2009) estimated the total cost of diabetes treatment at GHS 420,087.67 (US $300,062.62) with the total attendance of 776 clients per annum(Quaye, Amporful, Akweongo, &Aikins, 2015). This implied that each client spent $386.68 per annum. Currently, the minimum wage in Ghana is Ghc9.68. which is equivalent to Ghc3484.8 ($779.60) per annum. This puts households with diabetics in serious economic burden especially those with disabilities and complications.

In Ghana, the national health insurance policy eases the cost of healthcare rendered to Ghanaians including the diabetic patients. However, the NHIS in its current form does not cover all the essential healthcare services; and those costs that the NHIS does not cover patients have to pay what is popularly known in our hospitals as “Top Up”.

This study is therefore, seeking to assess the economic burden of diabetes management to households in Denkyembour District, Eastern Region.

1.2. Problem Statement

Globally, the cost of diabetes care continues to rise with its associated toil on patients and their households due to its chronicity and complications which need continuous management with medications, investigations, dietary and self-management in order to prevent complications and death. Thus for all age groups, the estimated direct annual cost of diabetes to the world is more than US$ 827 billion as the total global health-care spending on diabetes more than tripled over the period 2003 to 2013 (World Health Organization, 2016.). The results from cost of DM treatment by Seuring et al showed that a considerable impact of the disease in terms of costs to society, health systems, individuals and employers, and in terms of a reduction in the productive workforce and productivity in general is high (Seuring, Archangelidi, & Suhrcke, 2015). Majority of countries spend between 5% and 20% of their total health expenditure on diabetes which poses a significant challenge for healthcare systems and sustainable economic development (International Diabetes Federation, 2015). The menace of diabetes and its cost was estimated to have costed the Sub Saharan Africa US$67.03 billion annually, or US$8836 per diabetic patient per annum (Victoria Hall; Reimar W. Thomsen; Ole Henriksen and Lohse, 2011)

In Ghana, DM is a serious burden for households and the health system as the Diabetes Association estimated that there are about 4 million diabetics in Ghana of the 28 million population (Kwawukume, 2017).In Ghana, NCDs including diabetes cause an estimated 2.32 million disability-adjusted life years (DALYs) representing 10,500 DALYs lost per 100,000 population (Ministry of Health- Ghana, 2012). Denkyembour is one of the districts in Ghana with diabetes prevalence and a larger proportion of the population with low income. Thus the

records from St. Dominic Hospital showed that in 2016, 986 of the 2124 diabetics attending the hospital are from the district. Again the records from the district profile revealed that the people of Denkyembour are largely peasant farmers and therefore are poor. In fact, the St. Dominic Hospital Social Welfare is always inundated with the clients who are unable to settle their hospital bills. This is in line with the study by de-Graft et al which indicated thatNCDs including diabetes affect poor communities with the catastrophic costs of care driving them deeper into poverty (de-Graft, Addo, Ofei, Bonsu&Agyemang, 2012).

Urgent solutions with strong policies and programmes are seriously needed to address the aforementioned economic burden and the life threatening challenges pose by diabetes.And with regard to this, Ministry of Health stated that their NCDs policy goal is to ensure that the burden of NCDs including diabetes is reduced to the barest minimum so as to render it of little public health importance and an obstacle to socio-economic development (Ministry of Health- Ghana, 2012). As part of this goal, the Ministry of Health in their commitment to achieving SDG target of reducing mortality due to NCDs including diabetes by 30% by 2030, are seriously assessing the potential of reducing or lifting taxes on life saving medicines including insulin and syringes but also on some tests as HbA1c tests(Ghana Health Service, 2017).In order to implement such policies, an informed scientific evidence on economic burden of diabetes to households and the health system is needed. However, there is inadequate scientific evidence/studies on the economic burden of diabetes to households in Ghana, to inform cost effective policy implementation.

This study is therefore seeking to assess the economic burden of diabetes management on households in Denkyembour District, Eastern Region, Ghana.

1.3. Conceptual Framework

Diabetes is a chronic metabolic disease. It is a complex disease that needs continuous management/treatment with medications, investigations, dietary and self-management in order to prevent complications and death. This goes with cost and economic burden on the patient and household. The conceptual framework (Figure 1) below illustrates the relationship between diabetes mellitus and its economic burden on households.

The individuals with diabetes are faced with herculean task of having to solely depend on medical care and self-management so as to prevent complications and death. A huge cost is involved in managing the condition. The related cost to the disease include direct cost, indirect cost and intangible cost. The expenditure on medications, diagnostic investigations, consultation, admission, transportation, glucometers, blood lancets, insulin syringes are directly linked to direct cost while time lost to productivity due hospital visits, permanent disability and morbidity/mortality are linked to indirect cost. The lost to productivity as a result of physical pain, psychological pain and lack of focus due to mental stress and anxiety is being directly influenced by intangible cost.

The resultant cost of managing the condition (diabetes) is the economic burden on households of the clients.

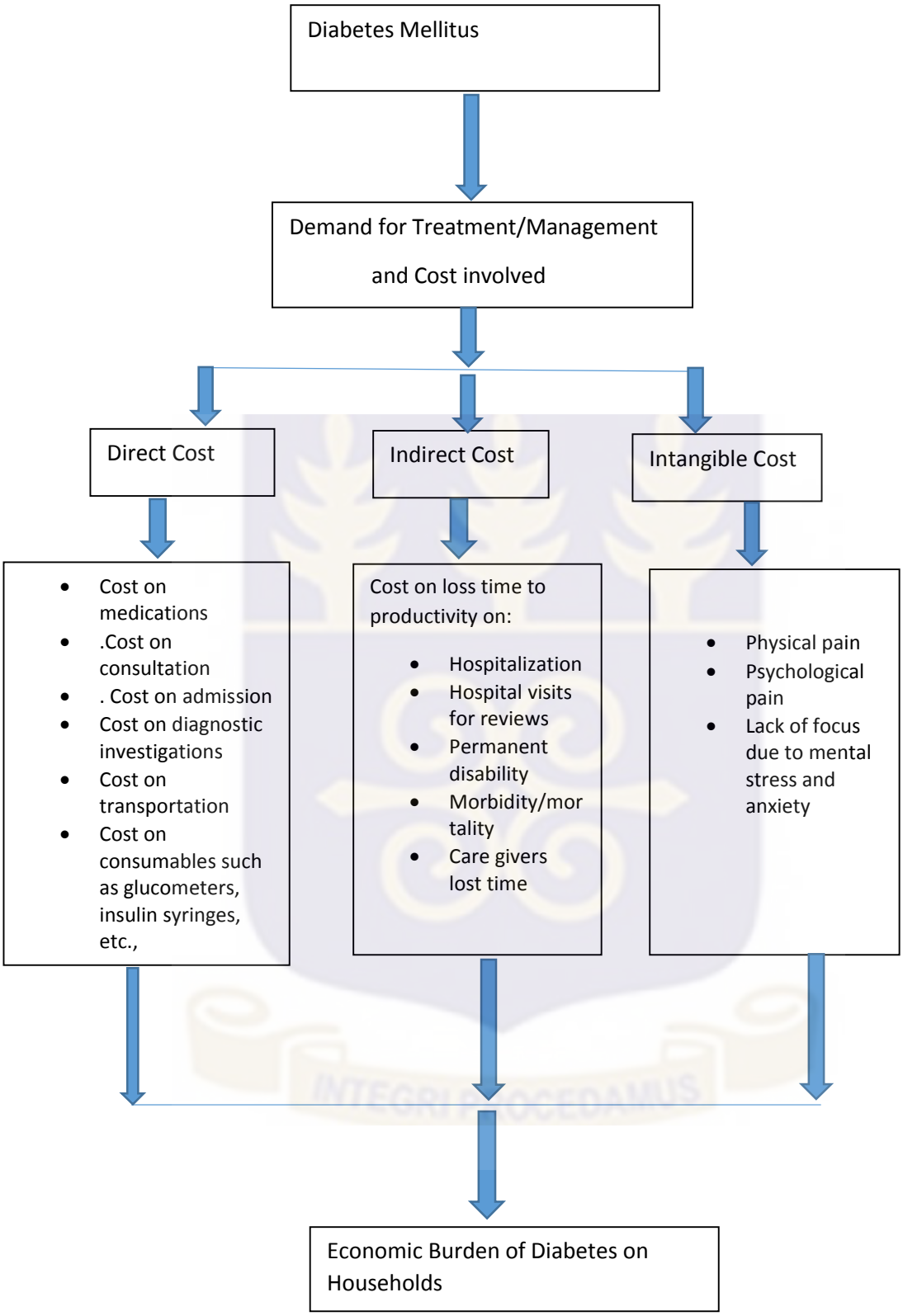

Figure 1: Conceptual framework on economic burden of diabetes to households

1.4.Study Justification

The study findings will highlight the cost of managing diabetes to households and the coping strategies households adopt to cope with costs associated with the disease.

The findings of this study may again, provide relevant information to policy makers which will guide policy formulations on DM management and its economic burden to households.

The findings of the study may also improve the clients and households knowledge on the cost involved in managing the condition. Clients and their caretakers' knowledge on direct, indirect and intangible costs, may help them plan their resources and treatment plan. It will also help them avoid risky behaviours; and take good care of themselves so as to prevent complications.

The findings of this study may also provide the healthcare professionals with information on the economic burden of diabetes management to households. This may inform their strategic planning, programmes and protocols that will be put in place to address the issues of waiting time, review schedules and cost elements of the care provided

1.5.Objectives

1.5.1 General Objective

The general objective of the study is to assess the cost of diabetes management to households in Denkyembour District

1.5.2 Specific Objectives

1. To estimate the direct cost of diabetes management to households
2. To assess the indirect cost of diabetes management to households
3. To ascertain the intangible cost of diabetes management to households

1.5.3. Research Questions

1. What is the estimated direct cost of diabetes management/treatment to households?
2. What is the indirect cost of diabetes management to households?
3. What is the intangibles cost of diabetes management to clients and households?

CHAPTER TWO

2.0. LITERATURE REVIEW

2.1.Introduction

This chapter reviews the existing literature on economic burden of diabetes management to households. It briefly presents background to diabetes as a disease. The literature provides information from global diabetes outlook, regional and country outlook and its associated economic burden. It then narrows to the main interest – the cost of managing diabetes which include direct cost, indirect cost, intangible cost, and the approaches for costs measurement and sensitivity analysis. The chapter ends with summary and conclusion of the literature.

2.1.1. Background of Diabetes as a Disease

Diabetes is a chronic metabolic disorder, which clinically presents with high blood glucose level. It comes as a results of reduced or absence of insulin secretion from the pancreas and/or reduced effectiveness of insulin in the tissues (insulin resistance). The absence or ineffectiveness of insulin in the tissues of the diabetics means that the glucose will remain circulating in their blood, and over time, the resulting high levels of glucose in the blood (known as hyperglycaemia) will then cause damage to many tissues in the body, leading to the development of disabling and life-threatening health complications (International Diabetes Federation, 2015). In 2015 it was estimated that there were 415 million people with diabetes aged 20–79 years, of which 5.0 million deaths attributable to diabetes. World Health Organization estimates that the worldwide hyperglycaemia is the third cause of premature deaths after arterial hypertension and smoking (Firănescu et al., 2016). Firănescu et al further reported that in sub- Saharan Africa, the

percentage of undiagnosed patients with diabetes is 66.7% (Firănescu et al., 2016) , "The Ghana Diabetes Association estimated that there are about 4 million Ghanaians living with diabetes in Ghana(Kwawukume, 2017). There are three major types of diabetes namely Type1, Type2 and gestational diabetes. Other experts have however, classified diabetes into four types using a group specific causes as the fourth type of diabetes.

2.1.2. Type 1 Diabetes

According to American Diabetes Association, type 1 which accounts for only 5–10% of those with DM, are caused by autoimmune destruction of Beta cells of the pancreas where the destruction involves islet cells which produce insulin(ADA, 2014). Aetiologically, two types are under this, namely autoimmune mediated type 1 and idiopathic type 1 diabetes. In T1DM, pancreatic β Cells make little or no insulin in response to insulin secretory stimuli with circulating levels of products of the β-cells (insulin, C-peptide and Amylin) in plasma at very low levels or absent and high glucagon level. T1DM patients require daily insulin injections to stay healthy and to prevent Ketosis (Diabetes Ketoacidosis, DKA), reduce hyperglucagonaemia and normalize lipid and protein metabolism.

2.1.3. Type 2 Diabetes Mellitus

Type 2 diabetes is a major medical, social and economic problem, due to the high prevalence and increasing incidence of the disease with subsequent progression of seriously disabling complications and need for specialized medical care(Tutelyan, Sharafetdinov, Plotnikova, Vorobiova, Kochetkova, Krul, Ouwehand and Mendelson, 2016)

Type 2 diabetes which is also known as insulin resistance diabetes, accounts for 90% to 95% of people living with diabetes(ADA, 2014). Globally, diabetes is set to rise from the current 382 million to 592 million persons within 25 years as it caused 5.1 million deaths in 2013; thus one death from diabetes in every six seconds (Tutelyan et al., 2016). This condition could be caused by abnormal beta cell functioning or resistance to the action of insulin or increased output of Glucose from the liver.

2.1.4. Diagnostic Criteria for Diabetes

According to the World Health Organization, the diagnostic criteria at which diabetes is diagnosed is as follows: fasting plasma glucose (FPG ≥ 7.0mmol/L), whole blood fasting plasma glucose (WBFPG ≥ 6.1mmol/L), plasma glucose 2hours after taking 75g of glucose (2hrPG ≥ 11.1mmol/L),random blood plasma glucose (RPG ≥ 11.1mmol/L), pregnant woman's fasting plasma glucose & plasma glucose 2hors after 75g of glucose intake (FPG ≥ 5.1 – 6.9mmol/L, 2hrPG ≥ 10.0mmol/L) and pre-diabetes fasting plasma glucose (FPG ≥ 6.1 mmol/L) (WHO, 2016b)

2.1.5. Complications of Diabetes

Diabetes is a chronic disease with deadly complications. The complications from diabetes are classified intomicrovascular andmacrovascular with the microvascular complications consisting of damage to nerves (neuropathy), renal system damage (nephropathy) and eye damage (retinopathy) while the macrovascular complications include cardiovascular diseases, and peripheral vascular diseases that may prevent wounds from healing leading to gangrene, and, ultimately amputation (Deshpande, Harris-Hayes, & Schootman, 2008). Cost of management of

these complications is huge; and therefore a source of economic burden to patients, their families and the health system at large.

2.2. Global Economic Burden of Diabetes

Globally, diabetes prevalence is becoming pandemic with the overall global health cost due to diabetes estimated at 673 billion US dollars (Ogurtsova et al., 2017). For all age groups, the estimated direct annual expenditure on diabetes to the world is more than US$ 827 billion as the total global health-care spending on diabetes more than tripled over the period 2003 to 2013 (World Health Organisation, 2016.). The direct and indirect cost including intangible cost of diabetes management is a burden for countries, households and families. In USA, the overall cost of diagnosed DMs was USD 245 billion, including USD 176 billion in direct medical cost and USD 69 billion in reduced productivity (Dall et al., 2013). Africa is the most affected region globally in economic burden of diabetes considering its 2017 GDP per capita which stood at USD 1,553.80 (World bank Group, 2018). The components of direct costs in France in 2010 were: hospital costs 37.2% (€4.9bn), outpatient costs (excluding drugs) 36% (€4.6bn) and drugs 26.8% (€3.5bn) while in Germany, the total direct cost burden arising from the treatment of people with diabetes has been estimated to be €43.2billion in 2010 with inpatient and outpatient direct costs for Type 1 & 2 being very close in proportion (33.7% versus 28.2%), while19.5% (€8.2bn) is expended on pharmaceuticals (both diabetes and non-diabetes related pharmaceuticals)(Köster, Huppertz, Hauner, & Schubert, 2011). The incremental cost of diabetes on health care costs increased from €12.9 billion in 2000 to €19.1 billion in 2007(Köster, Huppertz, Hauner, & Schubert, 2011) and €19.7billion in 2010. A comparison of diabetes DMP members versusnonmembers found non-significant higher annual hospital costs in nonmembers

(€1,277 versus €1,158/patient; 2006 costs) (Linder, Ahrens, Koppel, Heilmann & Verheyen, 2011).

Kirigia et al reported that about 7.02 million cases of diabetes recorded by countries of the African Region in 2000 resulted in a total economic loss of Int$25.51 billion (Kirigia et al., 2003). World Health Organization (WHO) in their publication, reported that public spending/expenditure constitutes the value of goods and services bought by the State, which includes provision of healthcareservices within a fixed budget scenario and increase in health spending which suggests a reduction in current or future spending opportunities on non-health services or goods (WHO, 2009).

A study conducted in four cocoa clinics in Ghana in 2009 estimated the total financial cost of diabetes management to the clinics to be at GHS 420,087.67 (US $300,062.62) with the total attendance of 776 clients per annum (Quaye, Amporful, Akweongo, &Aikins, 2015).

A study conducted in Mali on economic burden of diabetes indicated that the total cost of managing DM (Diabetes Mellitus) was almost 4 times higher than total cost of non DM conditions (DM= $281.92, NONDM= $77.08) with a difference of $204.84 (Tamayo, 2017). The annual total diabetes cost in the region was estimated at US$67.03 billion and US$8836 per diabetic patient(Hall; Thomsen; Henriksen; and Lohse, 2011). The results from cost of DM treatmentby Seuring et al showed that a considerable impact of disease in terms of costs to society, health systems, individuals and employers and in terms of a reduction in the productive workforce and productivity in general was high (Seuring, Archangelidi, & Suhrcke, 2015). A study conducted in Europe further revealed that the prevalence of diabetes and associated cost, including management of diabetes complications, are a growing concern (Kanavos, Van Den

Aardweg, & Schurer, 2012) The reviewed studies indicated that a large economic burden of diabetes, most directly affecting patients in LMICs with the magnitude of the cost estimates, differs considerably between and within countries (Seuring, 2015).

2.3. Cost of Illness

Even though morbidities and mortalities are the most used statistical measurement for the disease burden on population, they do not fully provide information on the burden of diseases to clients, households, countries and global community. Cost of illness (COI) assessment was however found to be one of the most effective measure of disease burden (Jo, 2014). The basic aim of cost of illness analysis is to assess the cost that illness imposes on society in general(Jo, 2014).

The financial burden posed by diseases and injuries are not only limited to the present situation; but also the health services and goods that may be paid for from savings or the sale of household assets, and thereby lead to depleted investment in (physical, financial and human) capital in the future(WHO, 2009)

An important economic consequence of disease or injury at the microeconomic level of households, firms and government is that, through its impact on functioning, individuals are unable to perform their usual day-to-day activities leading to loss of income or productivity which is a primary risk factor for impoverishment (WHO, 2009).

2.4. Cost of Diabetes Management

The fact that diabetes mellitus is a chronic disease that needs regular care and medications, means that the cost of managing it is also very expensive. The complications that come with diabetes makes it the most difficult condition to manage due to its cost of care. Diabetes places a large financial burden on individuals and their families due to the cost of insulin and other essential medicines and loss of productivity which is being further compounded by a permanent assistance required to overcome the related complications, such as renal failure, loss of vision or heart problems (International Diabetes Federation, 2015). Majority of countries spend between 5% and 20% of their total health expenditure on diabetes which poses a significant challenge for healthcare systems and sustainable economic development (International Diabetes Federation, 2015). The global total health costdue to diabetes was reported to be 673 billion US dollars with the highest proportion of healthcare expenditure spent on diabetes was in middle-income countries (12.5%), while the lowest proportion was spent in low-income countries (5.9%) while the proportion of 11.4% was spent in high- income countries (Ogurtsova et al., 2017)

The cost of illness (diabetes management) is measured using three key variables namely direct cost, indirect cost and intangible cost. Generally, the costs of illness is classified into three main groups namely direct, indirect, and intangible costs associated with health outcomes (Jo, 2014).

2.5. Direct cost of diabetes management

The direct cost of diabetes is comprised of cost incurred by patients, their households. WHO reports in 2016 revealed that diabetes and its complications bring about substantial economic loss to people having it and their families, and to health systems and national economies through

direct medical costs and loss of work and wages (WHO, 2016a). Direct medical costs is comprised of the cost of services provided by hospital, including inpatient stays, ICU stays, laboratory tests and other services provided outside hospitals: specialist and primary care doctor visits, community health worker, nurse, health educator, pharmacist, traditional practitioners and medication, while direct non-medical cost consists of cost of travel for treatment -to and from hospitals, waiting for admission, or time spent during institutionalized treatment- and paid caregivers (Bermudez-Tamayo, 2017). For all age groups, the estimated direct annual cost of diabetes to the world is more than US$ 827 billion as the total global health-care spending on diabetes more than tripled over the period 2003 to 2013 (World Health Organization, 2016.). World Health Organization reported that in Latin America, families pay between 40% and 60% of medical expenses from their own pockets, while in some of the poorest countries, people with diabetes and their families bear almost the total cost of medical care (World Health Organization, 2016.).

2.6. Direct Cost of Diabetes to Individuals/Households

A study conducted in USA in 2012 showed that $176 billion was spent in direct medical costs of diabetes management which comprised of hospital inpatient care (43% of the total medical cost), prescription medications on complications treatment (18%), anti-diabetic agents and diabetes supplies (12%), physician office visits (9%), and nursing/residential facility stays (8%); and out of which, people with diagnosed diabetes incur average medical expenditures of about $13,700 per year person (Dall et al., 2013).

Study conducted in Sudan in 2009 showed that the direct median annual expenditure of diabetes management during childhood was USD 283 per diabetic child, of which 36% was spent on

insulin, and for the adults the direct median cost of diabetes management of type 2 was USD 175 per year, which included the cost of drugs and ambulatory care which represent 23% and 9% of incomes of the families of the diabetic children and the adult patients, respectively, with more than half of the income of adults patients being contributed by the spouse or siblings(Ezat, Azimatun, Amrizal, Rohaizan, & Saperi, 2009). Another study done in Nigeria in 2015, revealed that the catastrophic diabetes expenditure (45% of the respondents income) is in excess of the 30 % threshold within the socioeconomic status; and is therefore, considered as high especially for the poorest who earnmeagre income but must buy at same rate with rich at the facility or forfeit treatment (Okoronkwo, Ekpemiro, Okwor, Okpala, & Adeyemo, 2015).

A study conducted in 2015 in Accra, Ghana reported that households who incurred expenditure in each cost category, the average cost of outpatient services, inpatient services, supplements, glucometer, transportation, food, loss of patients' income, payment for caregivers, and cost of complications were estimated to be GHS 1,282.00 per month (Pei, 2015). The study by Pei (Pei, 2015) further revealed that there is high economic burden of diabetes and its catastrophic effect on households, and the lack of financial protection among the households with diabetics in urban Ghana.

A study done by Ampofo in Tano North District of BrongAhafo Region, Ghana, revealed that the mean cost of seeking diabetic healthcare was GHS 146.60 (USD58.64) (SD=79.78) out of which the mean direct cost constituted was about 92.16% [GHS 135.10 (USD 54.20) (SD= 79.59) (Ampofo, 2014). This study again indicated that the mean direct cost of diabetic healthcare formed about 66.3% of the mean income [GHS 250.45 (USD 100.18) (SD=65.06)] of the respondents and about 41% of the patients spent more than 60% of their total income as direct cost of diabetes care. This means that direct cost alone takes a greater proportion of patients' income besides indirect and intangible costs being part yet.

Again, a study conducted by **(**Amon&Aikins, 2017**)** at Koforidua Regional Hospital, Ghana, reported that the total estimated direct cost (cost on medical and non-medical care) of type 2 was GHS 45,117.54 (USD 11, 568.60).

2.7. Indirect Cost of Diabetes

Indirect in cost of illness studies are referred to as productivity losses as a results of diseases and deaths on patients, relatives, public, or employers at large(Jo, 2014)

In some countries, the indirect cost of managing diabetes is higher than the direct cost. For instance, a study conducted in Mali in 2016 reported that indirect costs were larger than direct costs (61% vs. 39%) with negative impact of the condition and its complications mainly affects productivity (Bermudez-Tamayo, 2017).

An important economic consequence of disease and injury at the household level is that, through its impact on functioning, individuals are unable to perform their usual day-to-day activities thereby reducing productivity particularly in lower-income countries where employment opportunities tend to be dependent more on physical strength and endurance (WHO, 2009).

A study done in Morocco in 2013 reported that indirect cost on permanent disability, temporary disability and potential life years lost were US$ 1,486,940,942, US $19,832,628 and US $517,757,550 with total estimation around US $2 billion and average per capita for this indirect cost estimated to be US $1113 (Boutayeb, Lamlili, Boutayeb, & Boutayeb, 2013).

A research finding by Hall et al (2011) in USA, revealed that the estimated productivity loss associated with diabetes, $65 billion, came from higher levels of absenteeism, disability, and early mortality. For individual U.S. adults regardless of their diabetes status, diabetes imposes an

economic burden averaging $700 annually (Hall, Victoria; Thomsen, Reimar.; Henriksen, Ole; and Lohse, 2011).

Another study in USA reported indirect costs as follows: increased absenteeism ($5 billion) and reduced productivity while at work ($20.8 billion) for the employed population, reduced productivity for those not in the labor force ($2.7 billion), inability to work as a result of disease-related disability ($21.6 billion), and lost productive capacity due to early mortality ($18.5 billion) (American Diabetes Association, 2013).

Findings indicate that the indirect cost is on the rise. For instance, a study done by Logminiene et al. revealed that indirect costs during 28 years period increased 33 times, from 1.6 billion US dollars in 1969 to 54.1 billion US dollars in 1997 (Logminiene et al., 2004).

2.8. Intangible Cost of Diabetes

Intangible costs are those that reduce the quality of life, because of pain, anxiety and stress. Not only do they have a great impact on the lives of the patients and their families but also they are the most difficult to quantify. Diabetes treatment, particularly insulin injection and self-monitoring, can be time-consuming, inconvenient and uncomfortable.

A study in Tano, Ghana revealed that about 33% disclosed that they were often saddened due to their illness whereas 16.6% were saddened very often, and with about 20.3% often felt uncomfortable and stressed out with the routine insulin injections (Ampofo, 2014).The study also further revealed that some effects on quality of life of respondents due to diabetes mellitus included stress from routine medicine intake, losing babies due to diabetes, blurred vision and inability to work well, frequent weakness, polyuria and not being able to participate in family

activities as well as marriage issues due to sexual weakness which resulted in frequent quarrel due to sexual dissatisfaction (Ampofo, 2014)

A study by **(**Amon&Aikins, 2017**)** in Koforidua Regional Hospital, Ghana, showed that about 59% of the diabetic patients incurred moderate intangible cost, which was slightly higher in women (59%), with about 35% of the patients also reported of incurring low intangible cost, which was slightly higher in men (Amon& Aikins, 2017)**.**

A study done in Republic of Moldovia in 2015 revealed that monetary value of intangible costs was characterized by a large distribution, ranging from 790 to 52,600 Euros, with a mean value of 9,420 Euros with the monetary value of intangible costs being influenced by the disease activity and working status ($p<0,05$) (Sadovici, Cebanu, Mazur-Nicorici, Salaru, Vertrila, 2015).

2.9. Approaches for measuring cost of illness

Different studies have used various approaches in measuring cost of illness and for that matter the cost of managing diabetes. A study conducted by Grover et al in India used an approach that measured the economic burden of diabetes using the two cost estimates variables – the direct cost and indirect cost to help estimate the total cost of diabetes management(Grover, 2005). Again, a measurement of direct and indirect costs approach was employed by (Tamayo, 2017) to help estimate the cost of managing diabetes. The direct and indirect costs approaches used by these studies usually measure the direct medical cost, direct nonmedical cost, and cost on loss to productivity due diabetes to help estimate the economic burden of diabetes management. For instance, these approaches measure the direct medical and nonmedical costs including the indirect cost on productive/valued time lost due to diabetes-related temporary disability;

productive/valued time lost due to permanent disability; productive/valued time lost due to diabetes-related premature mortality; and the productivity loss due to the work time lost by relatives accompanying and visiting patients (Kirigia et al., 2003). Again, indirect costs of diabetes mainly related to productivity loss to absenteeism due to illness, early retirement due to diabetes, losses in productivity, dependence on social benefits and premature mortality and caregivers costs borne by family members (Kanavos et al., 2012). The two approaches above are similar although the study settings differs.

Another approach for estimating indirect costs according to (Anders, Ommen, Pfaff, Lüngen, Lefering, Thüm, 2013) is to measure the cost incurred through lost productivity that results from illness-related absences and the value of life estimation on the basis of its expected productivity by summing of the patients' gross monthly income and the employers' non-wage labor costs, which depend on the lost work days, that is on the time interval between the accident and the first work day (human capital approach). Many studies have not used this approach. This approach may be difficult to measure indirect cost for nonworking class.

2.10. Approach for intangible cost measurement

"Cost-of-illness studies (COI) can identify and measure all the costs of a particular disease, including the direct, indirect and intangible dimensions to provide estimates about the economic impact of costly disease" (Anders, Ommen, Pfaff, Lüngen, Lefering, Thüm, 2013). A study conducted in Germany by Anders employed Pirente et al. (2002) approach, the POLO-Chart, to enable the quantification of physical pain and social and psychological limitations in addition to the reduced physical functioning from which patients suffer following disease including the health-related quality of life (Anders, Ommen, Pfaff, Lüngen, Lefering, Thüm, 2013). The above

study used this approach in addition to direct and indirect costs. Productivity loss due to physical pain, psychological pain, depression and anxiety related to diabetes are used to measure the intangible cost.

Besides the traditional approach (direct, indirect and intangible costs estimates) outlined above, there are other approaches used in determining the economic burden of diseases.

2.11. Sensitivity analysis

Sensitivity analysis is a technique used to quantify the uncertainty in economic evaluation by varying the values given to a key variables in the valuation; and when key variables are identified, a plausible range of values is determined, and then the analysis is re-run using different values of the key variables, and the impact of these changes on the results is observed (World Health Organization, 2007). Sensitivity analysis can be conducted changing one variable at a time (one-way) or several (multi-way); and if the results of an economic evaluation change significantly with sensitivity analysis, they are generally less reliable for use in decision making(World Health Organization, 2007).

The variables in a cost-analysis study include cost of physician visits, price of medicines, cost estimate of adverse drug reactions (ADRs) experienced, laboratory tests required in the treatment, and duration of treatment (World Health Organization, 2007).

Some of the studies classified sensitivity analysis into one-way sensitivity analysis and probabilistic sensitivity analysis with the former (one-way sensitivity analysis), analyzed by varying the parameters according to the confidence intervals of the data, allowing researchers and reviewers to assess the impact of changes to a certain parameter on the model's results, while

the latter (probabilistic analysis) is understood to be a useful technique in quantifying the level of confidence that a decision maker has in the conclusions of an economic evaluation and cost of illness analysis(Jo, 2014). The results of one-way sensitivity analysis can be shown graphically in the form of a tornado diagram while in probabilistic sensitivity analysis, instead of assigning a single value to each parameter, computer software is used to assign a distribution to all parameters in the model based upon the average, the standard deviation, and the shape of the distribution of each parameter (Jo, 2014).

This study will employ the one-way and multivariate sensitivity analyses to test robustness and reliability of the cost estimates by varying the various components of the cost variables.

2.12. Conclusion

The literature review indicates variation of cost across countries and settings. Majority of studies reported direct cost to be higher as compared to indirect and intangible costs. The few studies reported indirect cost to be higher than direct cost.

Intangible cost as a variable/tool for measuring the economic burden of diabetes have not been used by some of the studies. The reviewed literature showed that those studies have merged the intangible cost with the indirect cost. But the studies that have used the intangible cost to estimate the economic burden of diabetes used physical pain, social and psychological limitations and reduced physical function as key factors/variables in measuring the cost. For instance the POLO-Chart, to enable the quantification of physical pain and social and psychological limitations in addition to the reduced physical functioning from which patients suffer following disease including the health-related quality of life

The reviewed articles showed the extent to which diabetes and its economic burden posed to the global health system, countries, and health facilities, with little information on households. The question is, if the healthcare facilities, national and global health systems are overwhelmed with this cost of managing diabetes, then what will be consequences on individual patients and their households? This question was not fully answered in the literature review as most of the studies globally gave little focus to economic burden of diabetes management to households.

This study will therefore, assess the cost burden of diabetes management to households in Denkyembour District of the Eastern Region, Ghana.

CHAPTER THREE

3.0 METHODOLOGY

This chapter outlines the details of the study area and the method which comprise of study design, sampling technique, sample size, data collection instrument, data analysis and ethical clearance. These procedures were described in detail so as to reflect the study objectives.

3.1. Study design

A descriptive cross sectional design was used to assess the economic burden of diabetes to households in Denkyembour District of the Eastern Region. It employed quantitative approach. The specific variables that were studied included direct cost, indirect cost, intangible cost, and overall cost and mean cost as well as estimated proportions. The study was carried out between5thJune and 7th July 2018. The study population was only diabetic clients from Denkyembour District who attended St. Dominic Hospital Diabetes Clinic. Only patients who were on treatment for one or more years were included in the study. Consent was sought from the patients with the explanation of the processes involved.

3.2. Study area

Denkyembour district is one of the forty-five districts and municipalities created in 2012 which was inaugurated on 28th June, 2012. The district was carved from Kwaebibirem District. The district is among twenty-six administrative districts and municipalities in the Eastern Region. Denkyembour District is located in the south-western corner of Eastern Region of Ghana. The

District shares common boundaries with Kwaebibirem District on the North, Akyemansa District on the West, Birim Central Municipal on South-West, West Akim Municipal on the South EastandEast Akim Municipal on the East.

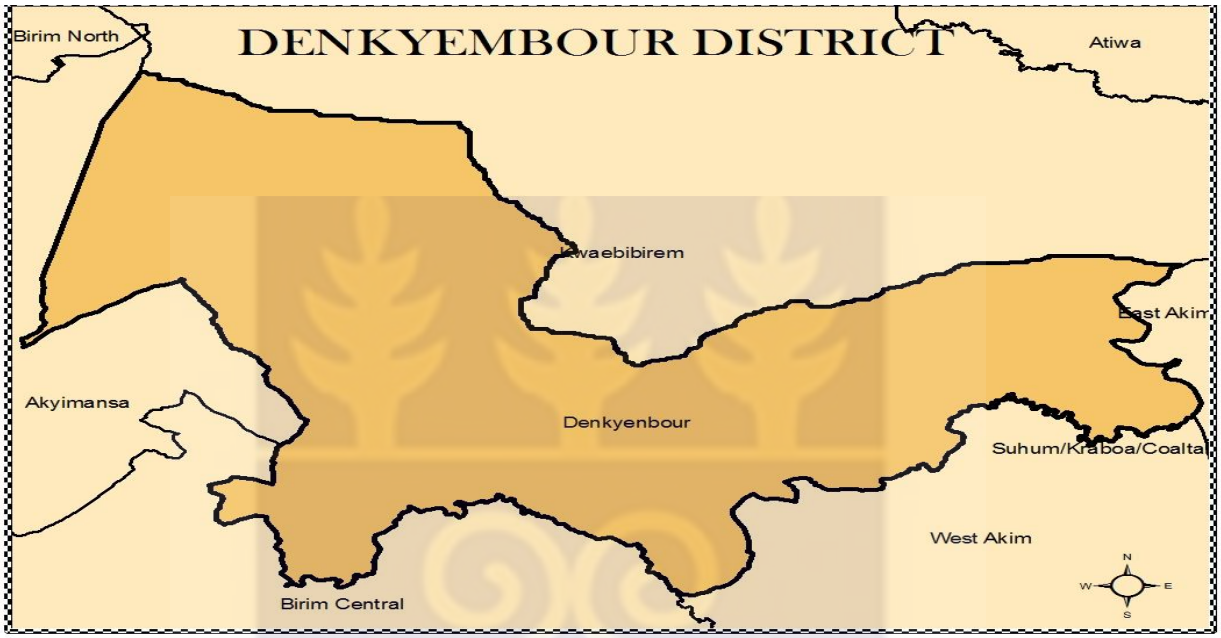

Figure 2: Map of Denkyembour District

The 2010 census estimates the then Kwaebibirem District population for 2012 which Denkyembour District was part to be 200,735 with a population growth rate of 2.1%. Currently, with the carving of the new district, Denkyembour population stands at 93,180

Temperature ranges between a minimum of 26.5^{o}C and a maximum of 27^{o}C. The District lies within the semi-equatorial climate zone with a double maximal rainfall regime. The District lies on the semi-deciduous forest zone and the vegetation consist of low-lying species of hardwood. Large plantations of teak have been cultivated outside forest reserves. The District has two (2) forest reserves to the east-Ayaola Forest and the West Atiwa Reserves-these together cover a very large area. The district can boast of arable land for the cultivation of cash crops like oil

palm and citrus as well as food crops like plantain, cassava, cocoyam among others. Economic or livelihoods activities in the district are peasant farming, petty trading and mining

Health service organization: The Management Structure in place at this level is the District Health Management Team. The Denkyembour has been sub-divided into six (6) sub-districts with health facilities dotted around. There are two hospitals namely St. Dominic Hospital and Ghana Consolidated Diamond (GCD) Hospital. The diabetes clinic is run in only St. Dominic Hospital. In 2016, diabetes was among the top five (5) morbidities in St. Dominic Hospital.

3.3. Sample Size Determination

There were 986 patients in the diabetic clinic register at the St. Dominic Hospital who were from Denkyembour District. Due to time constrain and cost, a representative sample was taken from this population with 95% confidence level and 80% power. The sample size was calculated using the average proportion from the previous academic works done by Ampofo(Ampofo 2015) and (Amon&Aikins, 2017). The cots (standard deviations) of these studies were 79.78 and 65.06 respectively. The average of the two costs was 72.42. By using this proportion, the sample size was calculated as follows:

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

Where: N is sample size, the critical z value, $z_{\alpha/2}$ is 1.96, the margin of error $E = 10$ and the previous studies standard deviation $\sigma = 72.42$.

$\Longrightarrow n = (1.96 \times 72.42/10)\ (1.96 \times 72.42/10) = 201.9 \approx 202.$

10% of the simple size was calculated and added to cater for nonresponse due to refusal to take part or illness (seriously ill clients). Hence the final sample size was 224.

3.4. Inclusion and Exclusion Criteria

3.4.1. Inclusion Criteria

The diabetic clients aged 18 years and above attending St. Dominic Hospital during the study period (28th May-8th June 2018). The respondents (diabetics) should have been on treatment for at least up to one year after diagnosis.

3.4.2. Exclusion Criteria

Those diabetics who were 18 years and above and did not consent to participate were excluded.

Those diabetics who were 18 years and above but on the day of interview were critically ill to participate, were also excluded

Diabetics who were on referral from other districts or did not reside in the district were alsoexcluded

Diabetic clients resident in Denkyembour District who were newly diagnosed with diabetes but had not started with treatment yet, were not included in this study

3.5. Sampling Procedure/Technique

Having identified the study population (sampling frame) who were within the inclusion criteria (diabetics from Denkyembour District, aged 18 years and above, on treatment for not less than

one year), and determined the sample size, a systematic sampling method was then used to select the respondents. A sampling interval (sampling fraction) was determined by dividing the sampling frame with the sample size (986/224 = 4.4 ≈ 4**).** Having obtained 4 as the sampling interval, 2 wasrandomly selected from the numbers 1, 2, 3 and 4. The respondents were then recruited starting from the randomly selected number 2 and systematically continued by selecting every 4th person until the sampling frame was exhausted and sample size reached.

After obtaining the sample, the individual patients who were being cared for by other people other than themselves, were followed up to their various homes for the data collection because those who were taken care of their medical bills did not come to the hospital with them. For the respondents (diabetics) who footed their own medical bills and were bread-winners in their families, the questionnaire was administered to them at the hospital. This was to ensure that the economic burden of diabetes to households were gathered from those directly paying for the care. The researcher had sought their consent and explained the procedure to them. The consent form was given to them (those who could read) to read and complete by filling it. For participants who could not read and write, the consent form was read out and explained to them in the presence of an independent witness, and had them thumbprint it before the information was taken. This was to ensure that every participant makes an informed decision before taking part in the study. To ensure privacy and confidentiality, no participant's name had appeared on the questionnaire. The data collected were coded with numbers. The questionnaire was assessed to ensure completeness, and filed appropriately.

3.6. Study variables

The main variable of interest in this study was the economic burden of diabetes on households, which was the outcome variable. The specific variables assessed were direct cost, indirect cost and intangible cost. The Table 1 below outlines the variables with their description.

Table 1: Study Variables

Variable (cost type)	**Variable Category (cost category)**	**Variable Description**
Direct cost	Direct medical cost	Cost of consultation Cost on medications Cost diagnostic investigations Cost on admission Cost on procedures due to complications Cost on glucometers, syringes/needles
	Direct nonmedical cost	Cost on transportation Cost on dietary management
Indirect cost	Productivity loss due to time lost	Visits to hospital for reviews Hospitalization Permanent disability Morbidity/mortality Caregivers time loss
Intangible cost	Productivity loss due pain & DM related mental disability	Cost on managing physical pain Cost on managing psychological issues Reduction in productivity due lack of mental focus

3.7. Quality control

3.7.1. Selection & Training of Research Assistants:

The research assistants selected had a minimum qualification of first degree in health related background and could communicate well in the local language spoken in Denkyembour District. Two training sessions were done before embarking on the data collection activity. The training touched on good understanding of the study objectives and the tool and its accurate interpretation. They were made to simulate how to create rapport, interpret tool and administer it to the respondents.

3.7.2. Pre-testing the Tool:

A pretestingwas performed at Kwaebibirem District and its hospital (Kade Government Hospital) where the characteristic features were similar to that of Denkyembour District and St. Dominic Hospital. This was to ensure that any problem or difficulty in the tool was corrected before the main research commences.

3.8. Data collection method

The information (data) was collected from the 224 clients through face-to-face administration of the questionnaire (closed ended questions) to them by the researcher and the research assistants. For the patients who were breadwinners and took care of themselves, the questionnaire was administered to them at the hospital; but for the individual patients who were being cared for by other people other than themselves, were followed up to their various homes for the data collection when those who were taking care of them were not with them at the hospital. This was to ensure that all the questions on the tool were answered more accurately and appropriately.

3.9. Data collection technique

A structured questionnaire (with close ended questions) was used for data collection. It collected the data on demography, socioeconomic variables and on the specific objectives which included direct cost, indirect cost, intangible cost and household income. The questions under the direct cost touched on the medical expenses (expenses on outpatient and inpatient services) and nonmedical expenses (transportation, feeding, miscellaneous) while the indirect cost covered the cost on time lost to productivity. Thus information was collected on all the key variables through the questionnaire. The data were collected from the respondents and or bread winners of the households.

3.10. Data processing

After collecting the data, returned questionnaires were reviewed to ensure that there were no missing values and errors. The data was then entered into the Microsoft excel version 2013. It was coded accordingly to ensure consistency, easy and accurate analysis. The data was also double entered to help identify data entry errors and clean it up.

A password was put on the data. This data can only be accessed by the researcher, supervisors and University of Ghana, School of Public Health. It will be destroyed in ten (10) years after the study. The cleaned data was then transferred to STATA Version 15 and analyzed.

3.11. Data Analysis

After the data processing, a descriptive data analysis was performed using Microsoft excel 2013 version and STATA Version 15. The analysis was based on the specific objectives (direct, indirect and intangible costs) of the study and sociodemographic factors as outlined below. The analysis also took into account whether the data were ordinal, nominal, dichotomous or continuous.

3.11.1. Sociodemographic and health status:

The categorical variables under the sociodemographic factors were analyzed and summarized into frequencies and percentages while the continuous variables under the same sociodemographic factors were also analyzed and summarized as means and standard deviations or percentages. The data were presented using tables, figures and charts.

3.11.2. Direct Cost and its estimation:

The direct cost of diabetes was made up of direct medical cost and direct nonmedical cost. Direct medical cost estimation was done by summing up all the cost incurred by the patients due to diabetes and its related complications on direct medical care/services such as consultation, diagnostic investigations, medications, other treatment (diabetic wound dressing, amputation, intravenous fluids), admission and consumables (syringes and needles, gloves, cotton). The mean cost of each of the cost elements above was estimated by adding the estimated cost on all the respondents and dividing it by the total number of respondents. The mean of the total direct medical cost was also determined by summing up all the estimated cost on all the cost elements under it. The confidence interval and the standard deviation of the direct medical cost were estimated. Table 2 below illustrates the estimation approach for direct medical cost on diabetes treatment

Table 2**: Estimation of Direct Medical Cost**

Cost Element (cost type)	**Respondents No.**	**Cost (GHS)**	**Mean Cost (95% CI)**	**Standard Deviation (S)**	**Cost Profile (%)**
Consultation	224	Summation of cost on consultation for all 224 respondents	The mean cost on consultation for all 224 respondents was estimated using STATA version 15	Standard deviation on cost of consultation was computed using STATA version 15	Percentage (proportion) of the cost on consultation was calculated
Diagnostic Investigations	224	Summation of cost on diagnostic investigation for all 224 respondents	The mean cost on diagnostic investigation for all 224 respondents was estimated using STATA version 15	Standard deviation on cost of diagnostic investigations was computed using STATA version 15	Percentage (proportion) of the cost on diagnostic investigation was calculated
Medications	224	Summation of cost on medications for all 224 respondents	Estimation of Mean cost on medications for the 224 respondents using STATA version 15	Standard deviation on cost of medications was determined using STATA version 15	Percentage on cost of medications
Admissions	224	Summation of cost on admissions for the 224 respondents	Estimation of Mean cost on admissions for the 224 respondents using STATA version 15	Standard deviation on cost of admissions was determined using STATA version 15	Percentage on cost of admissions
Other Treatment	224	Summation of cost on other treatment for the 224 respondents	Estimation of Mean cost on other treatment for the 224 respondents using STATA version 15	Standard deviation on cost of other treatment was determined using STATA version 15	Percentage on cost of other treatment
Total Direct Medical Cost	224	Summation of total direct medical cost for the 224 respondents	Estimation of mean cost on total direct medical cost for the 224 respondents using STATA version 15	Standard deviation on total direct medical cost was determined using STATA version 15	Percentage of the total direct medical cost was computed using STATA version 15

3.11.3. Direct Non-medical Cost:

This was estimated by summing up all the direct non-medical costs incurred by the patients in the process of managing their diabetic condition. The cost elements summed up here were the cost on transportation, feeding and other miscellaneous services. The mean cost of each of the cost elements mentioned above was estimated by adding the estimated cost for all the respondents and dividing it by the total number of the respondents. The mean of the total direct non-medical cost was also determined by dividing the total direct non-medical cost by the total number of the respondents. The confidence interval and the standard deviation of the direct non-medical cost were also be estimated. Table 3 below shows the estimation approach for direct medical cost on diabetes treatment

Table 3**: Estimation of direct non-medical costs**

Cost Element (cost type)	**Number of Respondents (N)**	**Cost (GHS)**	**Mean Cost (95% CI)**	**Standard Deviation (S)**	**Cost profile (%)**
Transportation	224	Summation of cost on transportation for the 224 respondents	Estimation of Mean cost on transportation for the 224 respondents using STATA version 15	Standard deviation on cost of transportation was determined using STATA version 15	Percentage (proportion) of the cost on transportation was calculated
Feeding	224	Summation of cost on feeding for the 224 respondents	Estimation of Mean cost on feeding for the 224 respondents using STATA version 15	Standard deviation on cost of feeding was determined using STATA version 15	Percentage (proportion) of the cost on feeding was calculated
Miscellaneous	224	Summation of cost on miscellaneous for the 224 respondents	Estimation of Mean cost on miscellaneous for the 224 respondents using STATA version 15	Standard deviation on cost of miscellaneous was determined using STATA version 15	Percentage (proportion) of the cost on miscellaneous was calculated
Total direct non-medical cost	224	Summation of total direct non-medical cost for the 224 respondents	Estimation of mean cost on total direct non-medical cost for the 224 respondents using STATA version 15	Standard deviation on total direct non-medical cost was determined using STATA version 15	Percentage of the total direct nonmedical cost was computed using STATA version 15

3.11.4. Total direct costs:

This was estimated by summing up all the estimated direct medical and non-medical costs incurred by the patients due to diabetes and its related complications. The mean, standard deviation and percentage of the total direct cost were also estimated through the use of STATA version 15. Table 4 below illustrates this.

Table 4**: The estimation of the total direct cost (direct medical and direct non-medical costs)**

Direct cost	**Number of respondents (N)**	**Cost (GHS)**	**Mean cost (95% CI)**	**Standard deviation**	**Cost profile (%)**
Total direct medical cos	224	Summation of total direct medical cost for the 224 respondents	Estimation of mean on total direct medical cost for the 224 respondents using STATA version 15	Estimation of standard deviation on total direct medical cost for the 224 respondents using STATA version 15	Estimation of the percentage on total direct medical cost for the 224 respondents using STATA version 15
Total direct non-medical cost	224	Summation of total direct medical cost for the 224 respondents	Estimation of mean on total direct non-medical cost for the 224 respondents using STATA version 15	Estimation of standard deviation on total direct non-medical cost for the 224 respondents using STATA version 15	Estimation of the percentage on total direct non-medical cost for the 224 respondents using STATA version 15
Total direct cost	224	Summation of total direct cost for the 224 respondents	Estimation of mean cost on total direct cost for the 224 respondents using STATA version 15	Estimation of Standard deviation on total direct cost for the 224 respondents using STATA version 15	Estimation of percentage on total direct cost for the 224 respondents using STATA version 15

3.11.5. Indirect Cost:

Here, the Human Capital Approach was used to analyze the indirect cost of managing diabetes. In estimating the indirect cost of diabetes care, all the productive working time (days) lost by each patient visiting a hospital for diabetes treatment or on admission with diabetes, were summed up and multiplied by the earnings each of those clients were making. All the analyzed and estimated cost elements (time lost due to hospital visits, time lost due to hospital admissions, inability to work due to disabilities caused by diabetes) in this section were summed up to give the total estimate of indirect cost**.** The estimates were expressed in productive value (monetary terms in GHS), mean, standard deviation and percentages.Table 5 shows the estimation approach for indirect cost of diabetes management.

Table 5**: Estimation of Indirect Cost**

Cost Category	**Number of Respondents**	**Productive days lost (days)**	**Mean, SD, % for days lost**	**Valued Productive days lost (GHS)**	**Mean, SD, % for valued productive days lost (GHC)**
Visit of diabetic clinic for reviews	Number of clients visiting hospital for care	Productive time (days) lost = summation of time spent by each client on hospital visits for diabetes care	The productive days lost were expressed in mean, SD and percentage using STATA version 15	Valued Productive days lost (GHS) = Days lost seeking for care × Earnings those clients could have made that period	The amount (GHS) was expressed in mean, SD and Percentage using STATA version 15
Admission to hospital with diabetes	Number of clients on hospital admission for diabetic care	Productive time (days) lost = summation of time spent by each client on hospital admission for diabetic care	The productive days lost were expressed in mean, SD and percentage using STATA version 15	Valued Productive days lost (GHS) = Days lost seeking for care × Earnings those clients could have made that period	The amount (GHS) was expressed in mean, SD and Percentage using STATA version 15
Disability due to Diabetes	Number of clients with disabilities due to diabetes	Productive time (days) lost = summation of time lost to work by each client due to disabilities resulting from diabetes	The productive days lost were expressed in mean, SD and percentage using STATA version 15	Valued Productive days lost (GHS) = Days lost seeking for care × Earnings those clients could have made that period	The amount (GHS) was expressed in mean, SD and Percentage using STATA version 15
Total indirect cost	Total number of clients (respondents) 224	Total number of productive days lost due to diabetes	Total Mean, SD and percentage of productive days lost due to diabetes	Total Valued Productive Days Lost (GHS) due to diabetes	Total mean, SD and percentage of Valued productive days lost (GHS) due to diabetes

3.11.6. Intangible Cost:

Since the intangible burden cannot be quantified, a descriptive analysis using a Likert Scale of five points were used to measure the degree or level of physical pain, psychological pain (depression, stress, and anxiety) and social effects due to diabetes.The rating on the degree of the event was 1 = None 2 = Mild, 3 = Moderate, 4 = Severe and 5 = So severe while that of the frequency of the event rated as 1 = Not at all, 2 = Occasionally, 3 = Often, 4 = Very often and 5 = Always. The level/degree of pain experienced was recorded in a linear form (range of 1 to 5), with higher scores indicating a higher burden of diabetes and lower quality of life. The composite intangible burden score was derived by summing up of intangible cost dimensions (ratings) under every cost variable (domain) such as physical pain, psychological pain and social effect suffered by diabetics, and multiplying the score with the number of questions. The total score was reclassified/divided into 3 categories namely low intangible cost (lower range limit of the score), moderate intangible cost (average range limit of the score) and high intangible cost (upper range limit of the score). The results were presented in frequencies, percentages and figures.

3.11.7. Overall Cost of Diabetes Treatment:

The total cost of diabetes management was estimated by summing up the total direct and indirect costs. The cost estimates reflected the entire cost incurred by the clients and their caregivers for a one month period. The intangible cost was not added to the total cost since it could not be quantified. However, its descriptive analysis with the Likert Scale was used to measure the degree/level or intensity of the physical pain, psychological pain and social effects people with diabetes went through. This indicated the level of diabetes burden on its victims. This burden diabetes definitely had a telling effect on individuals' economic situation since it could interrupt ones mental and physical capabilities.

Table 6**: Summary of methods in sampling, data collection and analysis**

Specific Objectives	**Variable**	**Scale of measurement**	**Sampling method**	**Data collection technique**	**Tool**	**Data Analysis**
To estimate the direct cost of diabetes management	Direct medical and non-medical costs	Nominal	Systematic random sampling of diabetics (n=224) of 18 years and above	Face to face interview	Structured Questionnaire	**Direct medical cost**: This was estimated by summing all the costs incurred on consultation, diagnostic investigations, medications, admission, syringes & needles, glucometers for diabetes treatment **Direct non-medical cost**: Summation of cost incurred on transportation, feeding and other miscellaneous services **Total direct cost:** This was estimated by summing up all the estimated direct medical and non-medical costs incurred by the patients due to diabetes and its related complications. Descriptive analysis (mean, standard deviation, percentages, frequencies, proportions) was employed using Microsoft Excel version 13 and STATA version 15
To estimate the indirect cost of diabetes management	Indirect cost	Nominal	Systematic random sampling of diabetics (n=224) of 18 years and above	Face to face interview	Structured Questionnaire	In estimating the indirect cost of diabetes care, all the productive working time (days) lost by each patient visiting a hospital for diabetes treatment or on admission with diabetes, were summed up and multiplied by the earnings (daily minimum wage). All the analyzed and estimated cost elements (time lost due to hospital visits, time lost due to hospital admissions, inability to work due to disabilities caused by diabetes) in this section were summed up to give the total estimate of indirect cost**.** Descriptive analysis (mean, standard deviation, percentages, frequencies, proportions) was employed using Microsoft Excel version 13 and STATA version 15
To estimate the total cost of diabetes management	Direct cost, Indirect cost	Nominal	Systematic random sampling of diabetics (n=224) of 18 years and above	Face to face interview	Structured Questionnaire	The total cost of diabetes management was estimated by summing up the total direct and indirect costs. Descriptive analysis (mean, standard deviation, percentages, frequencies, proportions) was employed using Microsoft Excel version 13 and STATA version 15
To determine the intangible cost of diabetes management	Intangible burden of diabetes	Ordinal	Systematic random sampling of diabetics (n=224) of 18 years and above	Face to face interview	Structured Questionnaire	A descriptive analysis (frequencies, mean, percentages and charts) using a Likert Scale of five points was used to measure the degree or level of physical pain, psychological pain (depression, stress, and anxiety) and social effects due to diabetes. STATA version 15 was used for the analysis

3.12. Sensitivity Analysis

Sensitivity analysis was used to quantify the uncertainties and robustness of the cost estimates. The sensitivity test was performed on medications and wage rates due to the uncertainties in the respondents' estimated values. Both the univariate (one-way) and multivariate (multi-way) sensitivity analysis were employed. First, the univariate analysis was used by varying the rates (medications and wage rates) individually by an increment of 4%, 6% and 8% (chosen by the researcher). This was followed by multivariate analysis in which both medications and wage rates were varied by an increment of 4%, 6% and 8%.

3.13. Ethical Consideration

The approval was sought from Ghana Health Service Ethics Review Committee (GHS-ERC). The GHS-ERC approval number is GHS-ERC075/01/18. Permission was obtained from the Diocesan Health Service, Eastern Region and St. Dominic Hospital, Akwatia as well as Denkyembour District Health Directorate. An introductory letter was obtained from the University of Ghana, School of Public Health to enable the researcher gain permission from the hospital. Informed and written consent were sought from the participants. The following explanations, information and reassurance were made available to respondents:

Duration of the interview: It took about 30 - 35 minutes to complete the questionnaire. The questions were explained clearly to the participants. Participants were encouraged to ask questions if they did not understand certain things.

Potential Risk: There was no physical risk involved in this study since no medical procedure had been carried out. However, the emotional and psychological stress that arose due to minor discomfort during the interview process, was allied by reassuring the respondent and explaining the processes involved, to them.

Benefits: The findings of the study will help improve the clients and households knowledge on the cost involved in managing the condition. Clients and their caretakers' knowledge on the management of the condition will help them plan their resources and treatment plan. It will also help them avoid risky behaviours; and take good care of themselves so as to prevent complications.

The study may also provide relevant scientific information to policy makers, and St. Dominic Hospital which could inform their policy decisions for the betterment of the clients.

Cost: There was no costs on any participants on whatsoever. The researcher and the assistants collected the data either at the participants' home or at the hospital depending on whether the client was the one taking care of his/her medical bills or there was (were) other people taking care of the cost. So there was no cost of transportation on the participants.

Compensation: There was no any monetary compensation for the participants.

Confidentiality: The respondents werereassured that their confidentiality and their liberty were protected. Thus the confidentiality of the respondents was protected by coding the data collected with numbers as identity instead of their names. No participant's name appeared on the questionnaire neither in any publication. Data were reported in aggregates to minimize traceability of respondents.

Privacy: To ensure privacy, the respondents were interviewed at an enclosed place that were convenient for them. One respondent was interviewed at a time. Nobody was allowed to participate except for those who were needed around by the respondent. The researcher tactfully carried out the interview in a manner that did not invade the privacy of the respondent emotionally.

Data Storage and Usage: To ensure data protection and participants' confidentiality, the entire questionnaire (data) collected will be securely locked up in a cabinet at the researcher's room. Password has been used to protect the data files. These data can only be assessed by the researcher, supervisors and the institution. All information collected from the participants will be destroyed in ten (10) years after the study. All storage materials like pen drives can only accessed by the researcher and supervisors.

Voluntary participation/Withdrawal: The participants were made to understand that participation or withdrawal from the study was voluntary; and that they have free will to participate or choose to stay away without any consequences on their medical care from the health facility. The consent form was given to them to read and complete by filling it. For participants who could not read and write, the consent form was read out and explained to them in the presence of an independent witness, and had them thumbprint it. This was to ensure that every participant makes an informed decision before taking part in the study.

Outcome and feedback: The participants will be told of the outcome of the research.

Appropriate alternative Procedures and Treatment: The alternative procedures and treatment was not applicable here. The respondents (diabetics) were rather strongly advised to adhere with the comprehensive management/treatment (glycemic management, complications management

and dietary/nutritional management) they were receiving at the St. Dominic Hospital Diabetes Clinic. They were also encouraged to adopt healthy lifestyles.

Funding Information: There was no funding for this study. It was funded by the researcher himself.

Conflict of interest: There was no any conflict of interest in this study. The study was purely for academic purpose. However, the information may be relevant to government, researchers, health facilities, clients and students.

3.14. Limitations

One of the limitations of this study was the likelihood of recall bias by the respondents. Thus some of the respondents might have not remembered the exact expenditure they had incurred in managing their diabetes, and therefore, may overestimated or underestimated the cost. To ensure a minimal recall bias, the principal investigator made sure that the research assistants were well trained on how to ask probing questions that aided the participants' recall of their treatment expenditure. This study used a recall of one month which is normally used for chronic diseases that require continuous care**.**

The total costs of diabetes management was limited to direct and indirect costs. Intangible cost was not included in total costs estimates because it could not be quantified in monetary terms. However, through a descriptive analysis of the intangible burden (physical pain, psychological pain, social effects) experienced by the respondents using the Likert Scale, the quality of life of the respondents were measured and the burden of diabetes determined.

CHAPTER FOUR

RESULTS

4.0. Introduction

This chapter presents the results of the study based on the study objectives. The sections of the chapter are made up of the sociodemographic characteristics of the respondents providing the profile of participants that may affect and inform the interpretation of the results, health status of the respondents (diabetics), direct cost, indirect cost, sensitivity analysis' and intangible cost.

4.1.Sociodemographic characteristics

A total of 224 diabetics were interviewed, with one respondent from the sampling frame replacing another person from the sample who was seriously ill. This represented 100% response rate.

Table 7 presents the sociodemographic characteristics of the study respondents. The mean age of the respondents was 56 years with minimum age of 19 years and maximum age of 85 years. A third of the respondents [30.8 % (69)] were between ages 45 - 54 and only 3.1% (7) aged between 18 - 34 years. Majority of the respondents to this survey, 56 % (127) were females. About 61.6% (138) of the respondents were married while 14.29% (32) divorced and 17.86% (40) widowed. The results further show that less than a third of the respondents, 28.6 % (64) had primary level education while 23.7% (53) had no level of education. Those who attained tertiary education level were 21% (47). Most of the respondents, 47.3 % (106) were self-employed.Those not earning income (unemployed, retired and students) constituted 40.6% of the respondents. The predominant occupation of the respondents was trading, 31.7% (71) and followed by farming with 29.91% (69).

The average monthly income of the earning diabetics was GHS 377.76 (USD 80.55), with the minimum and maximum earnings at GHS 100.00 (USD 21.32) and GHS 2,500.00 (USD 533.05) respectively. About 35.3% (79) were not earning any income. The other earning household members (192) average monthly income was GHS 385.29 (USD 82.15) and the minimum and maximum monthly earnings of GHS 180.00 (USD 38.38) and GHS 1,800.00 (USD 383.80.

Table 7: Sociodemographic characteristic of the respondents

Category	Number	Percentage
Age in years		
18-34	7	3.1
35-44	34	15.2
45-54	69	30.8
55-64	56	25.0
65 +58	25.9	
Mean: 55.76786,	Min age(19)	Max age(85)
Sex		
Male	97	43.3
Female	127	56.7
Marital Status		
Married	138	61.6
Divorced	32	14.3
Widowed	40	17.9
Not married	14	6.3
Education		
Tertiary	47	21.0
SHS/SSS	39	17.4
JHS/JSS	21	9.3
Primary	64	28.6
No education	53	23.7
Employment Status		
Employed-public	29	12.1
Unemployed	36	16.1
Self-employed	106	47.3
Retired	16	7.1
Student	8	3.6
Disable	31	13.8

Occupation			
Farming	67		29.9
Teaching	7		3.1
Nursing	3		1.3
Trading		71	31.7
Police	1		0.5
Artisan	14		6.3
Others	61		27.2
Monthly income (diabetics)			
GHS 50-300	40		17.9
GHS 301-500	58	25.9	
GHS 501-1000	21	9.4	
GHS 1001-1500	17	7.6	
GHS 1501& above	9	4.0	
Sub-total	145		64.7
Non-earners	79		35.3
Mean income (GHS): 377.76			
(95% CI):	(318.5048	437.013)	
Min - Max earnings:	100 -	2500	
Monthly income other household members			
GHS 50-300		58	25.9
GHS 301-500		66	29.5
GHS 501-1000		59	26.3
GHS 1001-1500	6	2.7	
GHS 1501& above	3	1.3	
Sub-total	192	85.7	
Non-earners	32	14.3	
Mean income (GHS):385.29			
(95% CI):	(347.78	422.80)	
Min - Max earnings:	180	1800	

US$1.00 equivalent to GHS4.69 (Bank of Ghana average monthly interbank exchange rate, July 2018)

Averagely, each household of the respondents had five people (mean=5.2) and five dependents (mean=5.0) with only one person (mean=1.2) making a monthly earnings. Minimum and maximum members of the respondents' households were two (2) and eleven (11) respectively.

4.2. Health status

The average blood glucose level was 6.99mmol/L (6.79 7.19) with the minimum and maximum values ranging from 4.3mmol/L - 14.6mmol/L.The average number of years these respondents lived with the diabetes was 9 years (95% CI: 8.47 - 10.15) while the minimum and maximum number of years were 1 and 26 years respectively.

About 57.6% (129) of the respondents had complications due to diabetes (Figure 3).

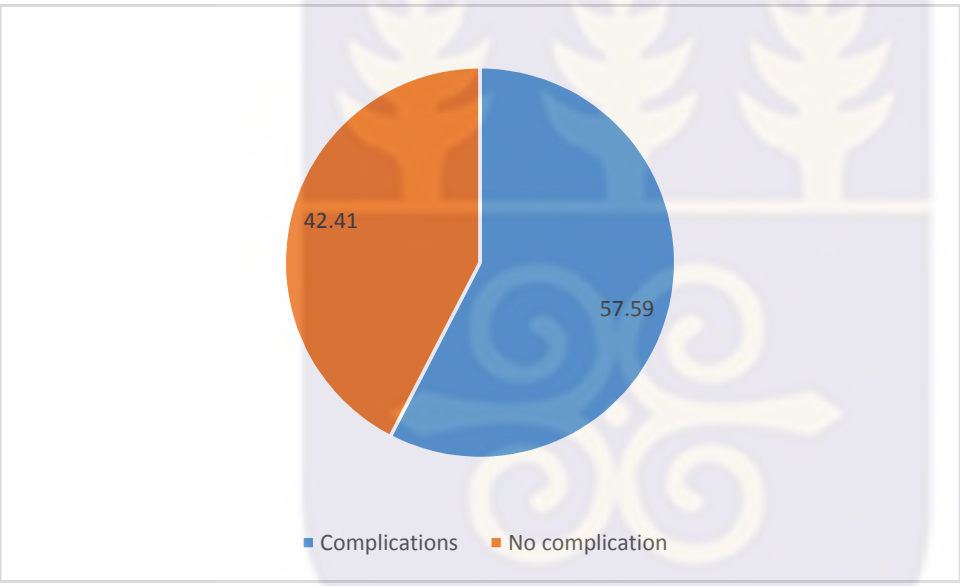

Figure 3: Proportion of respondents with complications and no complication

Those who suffered from hypertension were 42.9% (96) followed by neuropathy with 28.6% (64), eye problems with 24.6% (55), kidney disease 14.3% (32), foot ulcer 9.9% (22) and 4.9% for other complications (Figure 4).

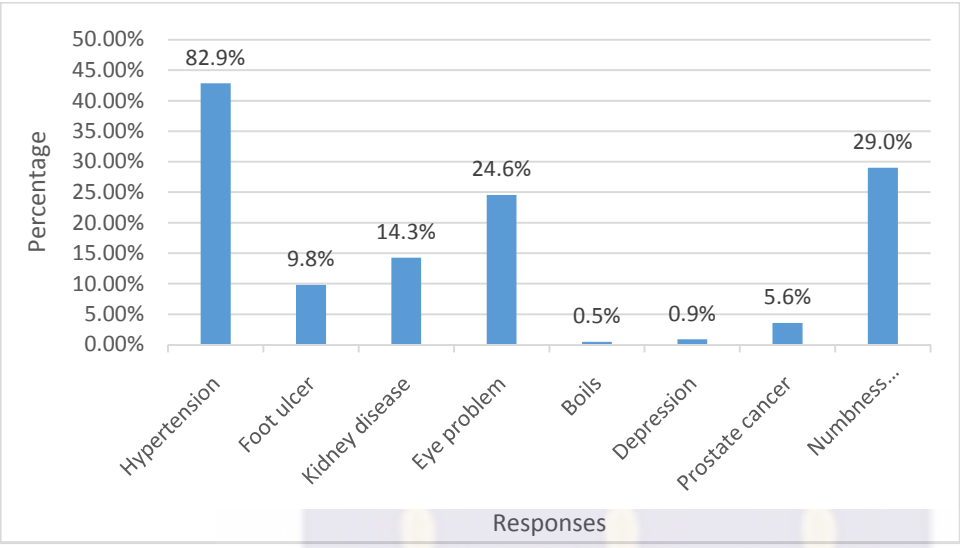

Figure 4: Distribution of complications among respondents

4.3. Direct cost

Direct cost was made up of two cost components namely direct medical and non-medical costs incurred by the respondents monthly due to diabetes treatment.

4.3.1. Direct Medical Cost

The cost elements of the direct medical cost were: consultation, laboratory services, scans, X-rays, oral medications, insulin, wound dressing, hospitalization (admission) and surgical procedures such debridement, amputation, etc. Table 8 presents the direct medical cost incurred by the diabetics monthly. The estimated total direct medical cost was GHS 35,200.47 with the estimated mean cost of GHS 157.14 (95% CI 145.30 168.99) and standard deviation of GHS 89.95. Oral medications made the bulk of the direct medical cost with cost profile of 64.2% followed by hospitalization (admission) with 9.7%. The one with lowest cost profile was scans which stood at 0.4%. The minimum and maximum costs were GHS 4.16 (Laboratory test) and GHS 175.00 (hospitalization).

Table 8: Direct Medical Cost

Cost Variable	N	Cost (GHS)	Mean (95% CI)	Standard Deviation	Cost Profile (%)	Min – Max Cost (GHS)
Consultation	224	2,394.70	10.69 (10.68 - 10.70)	0.08	6.8	10.00 - 10.70
Laboratory Tests	224	1,122.85	5.01 (4.50 5.52)	3.86	3.2	4.16 - 25.00
Scan	4	140.00	35.00	0.00	0.4	35.00 - 35.00
Oral Medications	224	2,2581.40	100.81 (95.73 105.89)	38.59	64.2	43.20 - 170.20
Insulin	67	2,702.40	40.33 (40.03 40.64)	2.35	7.7	36.00 - 41.60
Wound Dressing	23	2,590.00	112.61 (109.69 115.53)	22.20	7.3	90.00 - 150.00
Hospitalization	81	3,402.43	42.01 (37.65 46.36)	34.51	9.7	4.17 - 175.00
Surgical Procedures	14	266.67	19.05 (15.86 22.24)	25.28	0.7	6.25 100
Total (GHS)	224	**35,200.47**	**157.145 (145.30 - 168.99)**	**89.95**	**100**	**343.36 - 3,732.50**

US$1.00 equivalent to GHS4.69 (Bank of Ghana average monthly interbank exchange rate, July 2018)

4.3.2. Direct non-medical cost

The direct non-medical cost was made up of transportation cost, feeding cost, caregiver' feeding and transportation costs, and cost on miscellaneous. Table 9 presents the results of direct non-medical cost. The total direct non-medical cost was GHS 5, 224.50 (USD 1,113.97) with the mean cost of GHS 23.32 (USD 4.97)) and standard deviation of GHS 10.60 (USD 2.26). Under this component, the bulk of the cost was on transportation with the cost profile of 55.1% followed by feeding with cost profile of 28.8%. The one with least cost profile was miscellaneous which stood at 2.6%.

Table 9: Direct non-medical cost

Cost Variable	N	Cost (GHS)	Mean (95% CI)	Standard Deviation	Cost Profile (%)	Min - Max Cost (GHS)
Transportation (Diabetics)	224	2880.00	12.86 (11.83 13.89)	7.82	55.1	2 34
Feeding (Diabetics)	224	1506.50	6.73 (6.37 7.08)	2.73	28.8	2 15
Food & fare (Caretakers)	95	704.50	7.42 (6.93 7.91)	3.72	13.5	1 20
Miscellaneous	68	133.50	1.96 (1.77 2.16)	1.48	2.6	1 10
Total (GHS)	**224**	**5224.50**	**23.32 (21.93 24.72)**	**10.60**	**100**	**6 79**

US$1.00 equivalent to GHS4.69 (Bank of Ghana average monthly interbank exchange rate, July 2018)

4.3.3. Total Direct Cost of Diabetes Treatment

The total direct cost was made up of direct medical cost and direct non-medical cost (Table 10). The total direct cost was GHS 40,424.97 (USD 8,619.40), with the mean cost of GHS 180.47 (USD 38.48) and standard deviation of GHS 95.78 (USD 20.42). The direct medical cost made up the bulk of the direct cost with 87.1% (GHS 35,200.47).

Table 10: Total Direct Cost

Cost Variable	N	Cost (GHS)	Mean (95% CI)	Standard Deviation	Cost Profile (%)	Min – Max Cost (GHS)
Direct medical cost Consultation	224	2394.70	10.69 (10.68 - 10.70)	0.08	5.9	10.00 - 10.70
Laboratory Tests	224	1122.85	5.01 (4.50 5.52)	3.86	2.8	4.16 - 25.00
Scan	4	140.00	35.00	0.00	0.3	35.00 - 35.00
Oral Medications	224	22581.40	100.81 (95.73 105.89)	38.59	55.9	43.20 - 170.20
Insulin	67	2702.40	40.33 (40.03 40.64)	2.35	6.7	36.00 - 41.60
Wound Dressing	23	2590.00	112.61 (109.69 115.53)	22.20	6.4	90.00 - 150.00
Hospitalization	81	3402.43	42.01 (37.65 46.36)	34.51	8.4	4.17 175
Surgical Procedures	14	266.67	19.05 (15.86 22.24)	25.28	0.7	6.25 100
Subtotal (GHS)	224	**35200.47**	**157.14**	**89.95**		**58.06 474.90**
Direct non-medical cost Transportation (Diabetics)	224	2880.00	12.86 (11.83 13.89)	7.82	7.1	2 34
Feeing (Diabetics)	224	1506.50	6.73 (6.37 7.08)	2.73	3.7	2 15
Food & fare (Caretakers)	95	704.50	7.42 (6.93 7.90)	3.72	1.7	1 20
Miscellaneous	68	133.50	1.96 (1.77 2.16)	1.48	0.3	1 10
Subtotal (GHS)	**224**	**5224.50**	**23.32**	**10.60**		**6 79**
Total Direct Cost	**224**	**40424.97**	**180.47**	**95.78**	**100**	**68.06 516.90**

US$1.00 equivalent to GHS4.69 (Bank of Ghana average monthly interbank exchange rate, July 2018)

4.4. Indirect cost

Indirect cost was estimated from the productive time lost due to diabetes and its treatment (Table 11). Out of the total productive time of 328 days (7,872 hours) lost by the employed respondents as a result of the diabetes, about 80.8% of it (265 days) was attributable to time spent on hospitalization for treatment with monetary value of GHS 4,286.30 (USD 913.92)) and a cost profile of 49.0%. The productive time lost on monthly review by the diabetics (134) was 38 days (912 hours) with the monetary value of GHS 2,897.50 (USD 617.80)) and cost profile of 33.1%. The caregivers who were gainfully employed but had to give up work to care for the diabetic also lost 25 days (600 hours) representing a productive value of GHS 1,566.40 (USD 333.99) with cost profile of 17.9%. The total time lost by the employed respondents including the caregivers was 328 days (7,872 hours) and the mean time of 2 days (48hours). The total productive value lost was GHS 8,750.20 (USD 1,865.71).

Table 11: Indirect cost

Category	Cost Item	N	Productive Days Lost		Valued Productive Days Lost (GHS)		
			Days lost	Average days lost	Sum	Mean	Cost Profile (%)
Employed Diabetics	Admission period	30	265	8.83	4286.30	127.85	48.99
Unemployed Diabetics	Admission period	51	448	8.78	0	0	0
Employed Diabetics	Monthly reviews	134	38	0,28	2897.50	21.62	33.11
Unemployed Diabetics	Monthly reviews	90	25	0.28	0	0	0
Employed Caregivers	Monthly reviews	90	25	0.28	1566.40	17.40	17.90
Unemployed Caregivers	Monthly reviews	3	1	0.26	0	0	0
Total Employed		224	328	2	8750.20	39.06	100

US$1.00 equivalent to GHS4.69 (Bank of Ghana average monthly interbank exchange rate, July 2018)

4.5. Total cost of Diabetes treatment/management

The total cost of diabetes treatment/management was made up of direct cost and indirect cost. Table 12 below presents the total cost of diabetes management. The total cost estimate was GHS 49,175.17 (USD 10,485.11) with total mean cost of GHS 219.53 (USD 46.81). Direct cost accounted for 82.2% [GHS 40424.97 (USD 8,619.40)] of the total cost of managing the diabetes. The indirect cost was GHC8750.20 (USD 1,865.71) accounting for 17.8% of the total cost of diabetes management/treatment.

Table 12: Total cost of diabetes management/treatment

Cost Variable	N	Cost (GHS)	Mean cost	Cost profile (%)
Direct medical cost				
Consultation	224	2394.70	10.69	4.9
Laboratory Tests	224	1122.85	5.01	2.3
Scan	4	140.00	35.00	0.3
Oral Medications	224	22581.40	100.81	45.9
Insulin	67	2702.4	40.33	5.5
Wound Dressing	23	2590.00	112.61	5.3
Hospitalization: Monthly	81	3402.43	42.01	6.9
Surgical Procedures	14	266.67	19.05	0.5
Subtotal (GHS)	**224**	**35200.47**	**157.145**	**71.6**
Direct non-medical cost				
Transportation (Diabetics)	224	2880.00	12.86	5.9
Feeing (Diabetics)	224	1506.50	6.73	3.1
Food & fare (Caretakers)	95	704.50	7.42	1.4
Miscellaneous	68	133.50	1.96	0.2
Subtotal (GHS)	**224**	**5224.50**	**23.32**	**10.6**
Total Direct Cost (GHS)	**224**	**40424.97**	**180.47**	**82.2**
Indirect cost				
Time lost on admission	30	4286.30	127.85	8.7
Time lost on monthly review	134	2897.50	21.62	5.9
Time lost by caregivers	90	1566.40	17.40	3.2
Total Indirect Cost GHS	224	**8750.20**	**39.06**	**17.8**
Total Cost (GHS)	**224**	**49175.17**	**219.53**	**100**

US$1.00 equivalent to GHS4.69 (Bank of Ghana average monthly interbank exchange rate, July 2018)

4.6. Sensitivity Analysis

Table 13 below presents the sensitivity analysis. The sensitivity analysis was used to quantify the uncertainties and robustness of the cost estimates. The sensitivity test was performed on medications and wage rates due to the uncertainties in the respondents' estimated values. Both the univariate (one-way) and multivariate (multi-way) sensitivity analysis were employed. First, the univariate analysis was used by varying the two cost components (medications and wage rates) individually by an increment rate of 4%, 6% and 8% respectively.

The univariate sensitivity analysis conducted by varying the cost of medications by 4%, 6% and 8%, did yield to the increment of total cost of diabetes management by 1.8%, 2.7% and 3.5% respectively. The same analysis conducted on wage rate yielded a percentage increase of 0.7%, 1.1% and 1.4% in total treatment cost. However, the wage rate variations yielded lower increment rates than the medications.

Again, the direct cost of treating/managing diabetes was increased to 0.3%, 0.5% and 0.6% when the medications cost was varied by 4%, 6% and 8% respectively while that of indirect cost reduced by the same cost rates and variation rates. However, the indirect cost also got increased to 0.6%, 0.9% and 1.2% when the wage was varied by 4%, 6% and 8% respectively with the direct cost also decreasing with the same rates.

The concurrent variations (Multi-variate analysis) in both medications and wages by 4%, 6% and 8% resulted in a percentage fall in direct cost in proportions to total treatment cost, and a percentage rise in indirect cost in proportions to total treatment cost. This concurrent variations in both medications and wages at the same time did increase the total treatment cost by 2.5%, 3.7% and 4.8% respectively.

The results of the sensitivity analysis showed that the cost estimates of this study were sensitive to changes in wage and medications cost variables. However, the changes in the cost estimates were not so large. Hence, the findings of this study is reliable and therefore can be used for decision making.

Table 13: **Sensitivity analysis of total cost of diabetes treatment/management**

Scenario	Cost Component	Percentage Change in Parameter	Total Cost (GHS)	Percentage change in total cost	Proportion of total cost		Percentage change in proportion of cost	
					Direct	Indirect	Direct	Indirect
Base scenario		0	49175.17	0.0	82.2	17.8	0	0
Variation (One-way Sensitivity Analysis)	Oral Medications	4	50078.43	1.8	82.5	17.5	0.3	-0.3
		6	50530.05	2.7	82.7	17.3	0.5	-0.5
		8	50981.68	3.5	82.8	17.2	0.6	-0.6
Variation (One-way Sensitivity Analysis)	Wage	4	49525.18	0.7	81.6	18.4	-0.6	0.6
		6	49700.18	1.1	81.3	18.7	-0.9	0.9
		8	49875.19	1.4	81.1	18.9	-1.2	1.2
Multi-Variate (Two-way Sensitivity Analysis)	Oral Medications and Wage	4	50428.43	2.5	81.9	18.1	-0.3	0.3
		6	51055.07	3.7	81.8	18.2	-0.4	0.4
		8	51681.70	4.8	81.7	18.3	-0.5	0.5

US$1 = GHC4.79762 (Bank of Ghana Exchange Rate; July 10, 2018).

4.7. Intangible cost

The intangible cost components were categorized into physical pain, psychological pain and social effects associated with diabetes. The intangible cost burden was assessed using ordinal variables scale since it was unquantifiable.

4.7.1. Physical pain

Figure 13 presents the degree of physical pain among the respondents. About 33.0% (74) of the respondents had mild physical pain while 22.8% (51) had moderate pain and followed by 12.1% (27) with severe physical pain.Those who had no physical pain accounting for32.1% (72). Their physical pain was emanating from diabetic ulcers, insulin injections and general body pains due to diabetic ketoacidosis. Generally, about 67.9% (152) of respondents suffered some degree of physical pain. From the scale of one (1) to five (5), the physical pain was recorded as 2.15 (Table 14).

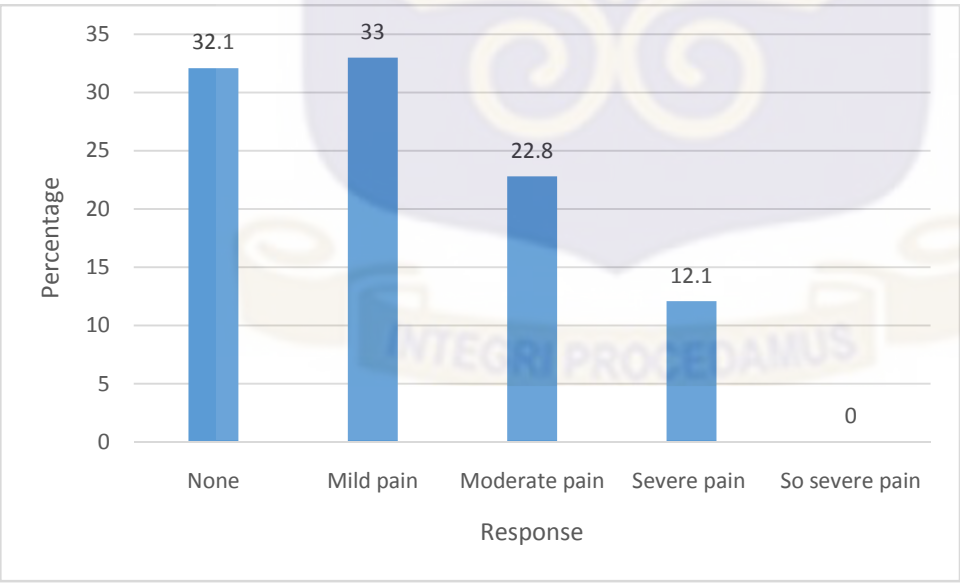

Figure 5: Degree of physical pain among respondents

Out of the 152 respondents who had physical pain, about 78.3% (119) of them had experienced the pain occasionally while 19.7% (30) experienced it (physical pain) often.

Also of the 152 respondents with physical pain, 65.1% (99) of them said the pain did not prevent them from working. However, the respondents who could not go to work whenever they experienced the physical pain rated it moderate (2.38) (Table14). The physical pain was emanating from diabetic ulcers, insulin injections and general body pains due diabetic ketoacidosis.

4.7.2. Psychological Pain

Majority; 96.4% (215) of the respondents indicated that they had psychological pain such as anxiety, mental stress and depression.

Out of the 215 (96.4%) of the respondents who had psychological pain, 48.8% (105) of them experienced the pain occasionally while 29.3% (63) experienced it often and 20.9% (45) suffered it very often.

About 50.7% (109) of the respondents indicated that the psychological pain did not prevent them from working, while 36.3% (78) of them indicated that psychological pain prevented them from working occasionally. Those who stated that the psychological pain prevented them from working very often were 10.7% (23).

The frequency of psychological pain was rated as 'occasional pain' (2.73), and inability to go to work whenever they (diabetics) experienced it (psychological pain) rated at 1.64 (Figure 14). The psychological pain was as a result of stress, anxiety and worries the respondents went through in the course of managing the diabetes.

4.7.3. Social effect

Under the social effects, the sexual life and marital issues with its associated effects were assessed. Thus 44.2% (99) of the respondents said they had sexual weakness due to diabetes and its medications. The results further indicated that 98% (97) of the respondents who had sexual weakness were males.

The results also demonstrate the level of marital problems among the respondents with sexual weakness. Thus 28.9% (26) of respondents had no marital problems while 17.8% (16) of them had marital problems often and 8.9% (8) had the marital problems very often. About 21.1% (19) of them (respondents with sexual weakness) had marital problem always.

The results further showed that out of the 44.2% (99) who had sexual weakness, 44.4% (40) of them were still married with no problem while 22.2% (20) were still married with few problems and 21.1% (19) were still married with many problems. The degree of marital problems due to sexual weakness was rated 2.7 (Figure 14).

Table 14: Intangible cost burden domain

Components of Intangible cost burden	N= 224	Percentage	Average score of
	N	experiencing event	event (Scale of 1– 5)
Degree of physical pain	152	67.9	2.15
Frequency of physical pain	152	67.9	2.24
How often physical pain prevents work	53	23.7	2.38
Frequency of psychological pain	215	96.4	2.73
Inability to work due to psychological pain	106	47.3	1.64
Degree of marital problems due to sexual weakness	99	44.2	2.7
Negative effects of divorce	11	4.9	4.45

The Figure 6 below presents the level of intangible cost burden. Majority (68%) of the respondents had moderate intangible burden while 29% had low burden and 3% high intangible cost burden.

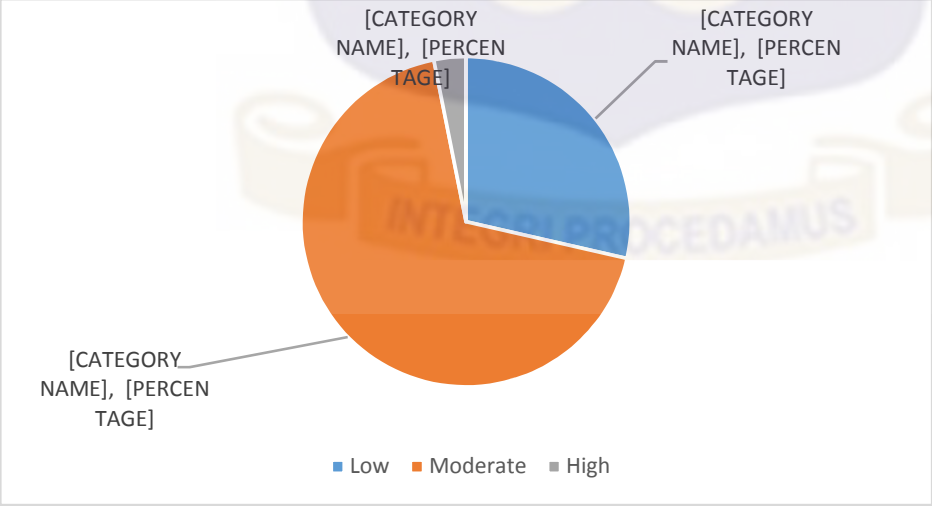

Figure 6: Composite intangible cost domain

4.8 Summary of Key Findings

- The mean age of the respondents was 56 years and modal age group of 45 – 54 years.
- The average monthly income of the earning respondents was GHS 377.76 (USD 80.55) with the minimum and maximum earnings ranging between GHS 100.00 (USD 21.32) – GHS 2,500 (USD 533.05) respectively.
- The households averagely had 5 dependents and 1 person earning monthly income.
- About 57.6% of the respondents had complications due to diabetes
- The total direct cost incurred by the respondents on diabetes management was GHS 40,424.97 (USD 8,619.40) representing 82.2% of the overall total cost.
- The total indirect cost was GHS 8,750.20 (USD 1,865.71), accounting for 17.8% of the overall total cost
- The overall total cost incurred by the respondents on diabetes management was GHS 49,175.17 (USD 10,485.11) with a mean cost of GHS 219.53 (USD 46.81).
- Majority (68%) of the respondents had moderate intangible cost burden while 29% and 3% had low and high intangible burden respectively.

CHAPTER FIVE

DISCUSSION

5.0. Introduction

This chapter presents the detail discussion of the study findings. The discussion is basically centered on the objectives of the study. It includes summary and discussion of the key findings of the study and its relation to published literature on the economic burden of diabetes management/treatment to households and society at large.

5.1.Sociodemographic Characteristics

The findings of this study demonstrate that diabetes is more prevalent among working population age group. Thus in this study, the mean age of the respondents is 56 years, with the modal age group of 45 – 54 years.This shows that most of the respondents were within the economically productive age bracket. This is similar to the finding made by (Zhuo et al., 2014) which reported the mean age of diabetics at 53.6 years. Similar findings was made by (Fernandes & Fernandes, 2017) where the mean age of the respondents was 51 years. This high prevalence of diabetes among the economically productive age group means that the income of the households of these diabetics will be affected negatively.

The finding of this study also indicates that the average monthly income of the earning diabetics is GHS 377.76 (USD 80.55), with the minimum and maximum earnings at GHS 100.00 (USD 21.32) and GHS 2,500.00 (USD 533.05) respectively. This is consistent with the finding by (Ampofo, 2014) which reported respondents' monthly income at GH¢ 250.45 (USD 100.18). Averagely, each household of the respondents of this study have five dependents (mean=5.03) with only one person (mean=1.16) making a monthly earnings. This in couple with the fact that

the average monthly cost of diabetes management is GHS 219.53 (USD 46.81) which constitutes 58.1% of the respondents' monthly income as per this study, shows that the monthly earnings of these diabetics are woefully inadequate to cater for them and their households. This is higher than the findings made from the study conducted in urban India among diabetics by (Chandra et al., 2014)which reported that average expenditure made on diabetes management was 23.7% of their income. This difference could be due to the difference in the income status of the two study populations or the difference in the cost of the health care services rendered.

5.2. Direct Cost

The findings of this study demonstrate that direct cost forms the highest share (82.2%) of the total cost of diabetes management. Thus the total direct cost of diabetes management in study is GHS 40,424.97 (USD 8,619.40), with the mean cost of GHS 180.47 (USD 38.48) and standard deviation of GHS 95.78 (USD 20.42). This finding is similar to the finding made by(American Diabetes Association, 2017) which reported that direct cost of diabetes management makes up 73% of its estimated total cost while indirect cost constituting 27% of the total expenditure. The finding of this study also corroborates with the observations made by (Chandra et al., 2014) where direct cost was found to be 69.1% of the total cost of diabetes treatment. Contrary to the finding of this study, is the study result by (Barceló et al,2003) which indicates that the direct cost of diabetic healthcare constitutes a lesser proportion (16%) of the total cost of diabetes management. The difference could be attributable to the difference in cost components of the two studies as well as cultural and sociopolitical, and health system policy structure differences.

In this study, direct medical cost made the bulk [GHS 35,200.47 (USD 7,505.43)] of the total direct cost, with the cost profile of 87.1%. This is consistent with the results of the study conducted in 46 countries of World Health Organization African region by (Kirigia, Sambo,

Sambo, & Barry, 2009) which showed that the direct medical cost made the bulk (92.8%) of the direct cost. It is also in consonance with the findings of study conducted by (Dall et al, 2013) which revealed that direct medical cost of DM healthcare constitutes 71.8% of the total direct cost.

Oral medications under this study made the bulk of the direct medical cost with cost profile of 64.2% followed by admission with 9.7%. This is similar to the study conducted by(American Diabetes Association, 2017) which indicates that medication forms 43% of the direct medical cost.Similarly, a study finding by Chandra et al (2014) also reported that medicines constitute the higher percentage (52%) share of direct medical cost on diabetes treatment expenditure. This makes medications very important cost element as far as cost of diabetes management is concerned.

5.3. Indirect cost

The cost burden of diabetes management is not limited to direct cost on medications, investigations, hospitalization, procedures and other non-medical direct cost alone. It includes other indirect cost components such as productive time lost by the diabetics and their caregivers in their quest to seek treatment, or productive time lost due permanent disability caused by diabetes. The findings of this study indicates that the total indirect cost (valued productive time lost) on diabetes management is GHC 8,750.20 (USD 1,865.71) with the mean indirect cost of GHS 39.06 (USD 8.33). This constitutes 17.8% of the total cost of diabetes management/treatment. Although, this is less than direct cost, it is very significant. This finding is consistent with the results of the study conducted by Chandra et al. (2014) which found the indirect cost of diabetes management to be 30.9% of the total cost. Again, in consonant with this

study is the finding byChatterjee et al. (2011) which reported that the indirect cost of diabetes management is 37% of its total treatment cost, and that it is less than direct cost though significant. The American Diabetes Association (2013) also reinforces the finding of this study through its research finding which indicated that total indirect cost is 28.2% of the total cost of diabetes management.

However, some of the studies have reported thatindirect cost of managing diabetes is higher than the direct cost. For instance, a study conducted in Mali by Bermudez-Tamayo (2017) reported that indirect cost is larger than direct costs (61% vs. 39%) with negative impact of the condition and its complications mainly affecting productivity. Another study results by Barceló et al (2003) also indicated that the indirect cost of diabetic healthcare constituted a higher proportion (83.6%) of the total cost of diabetes management.The difference here could also be attributable to the difference in cost components of the two studies. For instance, Barceló et al (2003) included cost on mortalities under its indirect cost elements which this study did remove following the pre-testing of the tool. The respondents' cultural understanding of death was largely the reason why they shied away from answering the questions on mortality cost.

5.4. Total cost of diabetes treatment/management

The findings of this study demonstrate that the overall estimated cost of diabetes management is very expensive and burdensome to the diabetics and their households. The overall total cost estimate for diabetes treatment in a month in this study is GHS 49,175.17 (USD 10,485.11) with the total mean cost of GHC 219.53 (USD 46.81). This is lower than the findings made from the study done in United State of America on economic burden of diabetes by (Timothy et al., 2010) which reported higher mean total cost ($831.25 per month) than this study. The differences in the

cost could be due to difference in exclusion and inclusion criteria employed by the two studies where Timothy et al included pre-diabetes and newly diagnosed diabetics and on the other hand this study excluded pre-diabetes and diabetics under one year of treatment and below 18 years old.Per this study's finding, the estimated direct cost constitutes the bulk of the total treatment cost with a cost profile of 82.2% as compared to total indirect cost which constituted 17.8% of the total treatment cost.This is similar to the results of the study conducted by American Diabetes Association (2017) which reported direct cost at 72.5% of the total cost.

With the average monthly earnings of the respondents at GHC 377.76 (USD 80.55) andthe total mean cost of managing the condition at GHS 219.53 (USD 46.81) as per this study, means that the diabetics and their households spend 58.1% of their monthly earnings on diabetes management. This brings serious economic burden to the diabetics and their households.

5.5. Intangible cost (burden)

The cost of diabetes management is not limited to direct and indirect cost components alone. It includes intangible cost component such as physical pain, psychological pain and social effects associated with diabetes.Research conducted in the WHO African region on the economic burden of diabetes, by Kirigia et al (2009) stressed that the intangible costs incurred on the management of diabetes contributes significantly to overall cost attributable to the disease. In this study, 67.9%

(152) of the respondents had experienced some degree of physical pain which most (68%) of them rated as moderate pain. This corroborates the results of the study conducted in northwest of England among diabetics by (Abbott, Malik, Van Ross, Kulkarni, &Boulton, 2011) which reported that 26% of diabetic patients without neuropathy and 60% of the diabetics with severe

neuropathy had physical pain. The physical pain under this study was emanating from diabetic ulcers, insulin injections and musculoskeletal pains due to diabetic ketoacidosis.

Again, the results of this study show that majority (96%) of the diabetics suffer psychological pain such as anxiety, mental stress and depression. This is similar to the study conducted by (Selvarajah et al., 2014) which reported that 51.4% of the diabetics attending Sheffield Teaching Hospital, England, had emotional distress with suggestive clinical anxiety and depression. A study done in USA among adult diabetics by (Egede, 2004) also revealed thatindividuals with diabetes and comorbid major depression were 58.1% and 77.8% respectively Again, the majority (68%) of the respondents from this study rated psychological pain as moderate. This is also similar to the results of the study carried out in Australia by Donald et al. (2012) which indicated that about 42% of diabetics lived with pain and discomfort, and 34% were depressed with anxiety related tendencies.

Under the social effects, the sexual life and marital issues with its associated effects assessed by this study indicates that 44.2% (99) of the respondents had sexual weakness due to diabetes and its medications. Out of the 99 respondents who had sexual weakness, 97 (98%) of them were males. This is consistent with the findings made from the study conducted in Istanbul, Turkey by (Erden& Kaya, 2015) which showed that 82% of male diabetics studied had experienced erectile dysfunction.In this study, only 28.89% (26) of the respondents with sexual dysfunction had no marital problem at all. The rest had some level of marital problems. This is consistent with the cross-sectional study

conducted in Tema General Hospital by (Owiredu et al., 2017) which revealed that the mean Sexual Quality of Life (SQoL) and Partners' Sexual Quality of Life (SQoL-Partner) for the diabetic males and their partners was 42.29±30.88 and 52.86±15.26, respectively.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

This chapter summarizes the major findings of study and its implications and relevance, and offers recommendations that will help inform policies and programmes that will be geared towards the improvement of the current focus and management of diabetes and to address its high economic burden to households in Denkyembour District and Ghana at large.

6.1 Conclusions

Diabetes is a complex disease that needs continuous management/treatment. This comes with high cost. Direct, indirect and intangible costs were measured to determine the economic burden of diabetes management to households in Denkyembour District.

The findings of this study indicate that the total monthly cost of diabetes management is very expensive for the patients. Thus the monthly total cost of diabetes management per this study is GHS 49,175.17 (USD 10,485.11) with total mean cost of GHS 219.53 (USD 46.81). This means the diabetics spend 58.1% of their monthly earnings (GHS 377.76) on DM management.

Direct cost accounted for the highest proportion (82.21%) of the total cost of managing diabetes under this study. Medications constitute 64.2% of the total direct medical cost, 55.9% of the total direct (direct medical and direct non-medical) cost and 45.9% of the overall total cost. This suggests that medications are very important factor in the cost of diabetes management and therefore should be given necessary attention by the stakeholders and government to help reduce economic burden of diabetes to patients and their families.

Indirect cost (valued productive time lost by diabetics and their caregivers) constitutes lesser proportion (17.8%) of the total cost of diabetes management under this study. Though lesser proportion, this is very significant considering the income level of the respondents and the fact that this is spent every month.

Besides the direct and indirect costs, the diabetics also incur intangible cost.Most of the respondents in this study have experienced some level of psychological pain, physical pain and social effects. Majority (68%) of them rated intangible burden as moderate while 29% and 3% rate it as low and high intangible cost burden respectively.

The study therefore, concludes that the combine effect of direct, indirect and intangible costs of diabetes management put patients and their households into serious economic burden.

6.2 Recommendations

Per the findings of this study, the following are recommended:

1. NHIS should cover the full cost of direct medical care especially medications which constitute the largest percentage of total cost of DM management under this study
2. Psycho-social care and support should be made part of diabetes management to help alleviate psycho-social pains among diabetics and their families.
3. The policy makers and health institutions should institute pain management protocol to alleviate the physical pain suffered by the diabetics. This will reduce the intangible burden
4. The unit cost on each cost element in this study can be used by the health system policy makers as a vital data to formulating good policy interventions on DM management

5. Patients, households and health institutions can also use these cost data to budget for diabetes management

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APPENDICES

Appendix I: Participants' Information Leaflet

This leaflet shall be given to all the prospective participants to ensure that they all have enough knowledge and understanding of the Research before deciding whether to take part in the study or not to partake.

Research Title: Assessment of the Economic Burden of Diabetes Management/Treatment to Households in Denkyembour District, Eastern Region, Ghana.

Background: The study is being carried out by Mr. Adam Joseph, a student from the University of Ghana, School of Public Health, as part of the requirement for the Master of Public Health programme.

The aim of the study is to estimate the economic burden of diabetes to households. A structured closed-ended questionnaire will be used for data collection. The data to be collected will include all the study objectives and sociodemographic characteristics of the participants. For the participants who are on NHIS and other insurances, information concerning how much they pay and how much the schemes are paying will be obtained from the hospital's records. The study population (224) is made up of both sexes aged 18 years and above who reside in Denkyembour District and diagnosed with diabetes or household heads and caregivers sampled.

It will take about 30 to 35 minutes to complete the questionnaire. The questions will be explained clearly to the participants. Participants will be encouraged to ask questions if they do not understand certain things.

There will be no any risk involved in this study either physically, psychologically or socially since no medical procedure is going to be carried out. Their privacy and liberty is assured. All the data collected will be coded with numbers. No participant' name will appear on the questionnaire neither the publication. They have free will to participate or choose to stay away without any consequences on their medical care from the health facility. Participants' congeniality is paramount and therefore assured.

The participants will gain knowledge on how to manage the condition and the cost involved. They will also have insight about the coping strategies in the management of the condition.

There shall be no costs on any participants on whatsoever. The researcher and the assistants will collect the data either at the participants' home or at the hospital depending on whether the client is the one taking care of his/her medical bills or there is (are) other people taking care of the cost. So there will be no cost of transportation on the participants.

There shall be no any monetary compensation for the participants. A toking may be given to them by the researcher. They will also receive free health education from the researcher.

To ensure data protection and participants' confidentiality, the entire questionnaire (data) collected will be securely locked up in a cabinet at the researcher's room. Password shall be used to protect the data files. This data can only be assessed by the researcher, supervisors and the institution. All information collected from the participants will be destroyed in ten (10) years after the study. All storage materials like pen drive can only be accessed by the researcher, supervisors and the School of Public Health. The participants will be told of the outcome of the study if they seek for it, but the data will not be made available to them.

The researcher has no sponsors. The study is being funded by principal investigator himself.

There is no any conflict of interest in this study. The study is purely for academic purpose. However, the information may be relevant to government, researchers, health facilities, clients and students.

In case of any concern, you can contact the researcher, Mr. Adam Joseph on 0246284813, joseph.adam54@yahoo.com or Dr. Patricia Akweongo on 0243138376.

Appendix II: Consent Form

A Statement of the Person obtaining the Informed Consent

I have fully explained the Research Study to ……and have given enough information about the project work, its benefits, risk, processes in the data collection and the purpose of the study to all the prospective participants in order to inform their decision on whether to take part in the study or not.

NAME ……SIGNATURE …… DATE …….

Statement of person giving consent:

I have read the information on this research study; or have had it translated into the language I understand. I have also had my questions answered by the interviewer to my satisfaction.

I understand that my participation is voluntary and not compulsory.

I know enough about the purpose, methods, risks and benefits of the research study before I decided to participate

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: …… SIGNATIURE/THUMPPRINT: ……

DATE: …….

Statement of person witnessing consent (For non-literate participants):

I ……..certify that information given to……

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

WITNESS' SIGNATURE/THUMB PRINT …… DATE ……..

Appendix III: Research Questionnaire

The Research Title: Assessment of Economic Burden of Diabetes Management/Treatment to Households in Denkyembour District, Eastern Region

Dear Participant,

Good morning /afternoon! My name is Adam Joseph, an MPH student from the University of Ghana, School of Public Health. I am conducting this research in Denkyembour District to assess the economic burden of diabetes treatment to households. I will therefore ask of few minutes of your precious time to enable you answer the following questions concerning the topic (economic burden of diabetes) above. Your opinion is very essential and therefore express yourself freely. Be assured that all the answers you are going to give are strictly confidential; and that your name shall not be mentioned anywhere in the report or anything. Thank you very much.

Tick [√] where appropriate. Also fill in on the spaces provided with the doted lines (…….)

Sect/Qn # **Section 1**	**Question** **Sociodemographic Characteristics**	**Response**	**Code**
1	What is your age?	……. Years	
2	What is your sex?	1. Male [ ] 2. Female [ ]	1 2
3	What is your marital status?	1. Married [ ] 2. Divorced [ ] 3. Widowed [ ] 4. Not married [ ]	1 2 3 4
4	What is your educational level?	1. Tertiary [ ]	1

		2. SHS/SSS [ ]	2
		3. JHS [ ]	3
		4. Primary [ ]	4
		5. Has not been to school [ ]	5
5	What is your employment status?	1. Employed [ ]	1
		2. Unemployed [ ]	2
		3. Self-employed [ ]	3
		4. Retired [ ]	4
		5. Student [ ]	5
		6. Disable [ ]	6
6	What is your occupation?	1. Farming [ ]	1
		2. Teaching [ ]	2
		3. Nursing [ ]	3
		4. Doctor [ ]	4
		5. Trading [ ]	5
		6. Lawyer [ ]	6
		7. Police [ ]	7
		8. Artisan [ ]	8
		9. Others [ ]	9
7	How much do earn a month?	GHC …….	
8	How many people are in your household?	…….	
s9	How many of them depend on the income?	……	
10	How many of them make earnings?	……..	
11	How much is their earning in a month?	Person 1: GHC …….. Person 2: GHC …… Person 3: GHC ……	

		Others: GHC …… Total: GHC ……	
12	What kind of house do you live in?	1. Story building [ ] 2. Self-contained house [ ] 3. Compound house [ ] 4. Mud house [ ]	1 2 3 4
13	How many bed rooms are there in your house?	……	
14	Does your household have the following functional items?	1. Car(s) Yes[ ] No[ ] 2. Motorbike(s) Yes[ ]No [ ] 3. Bicycle(s) Yes[ ] No[ ] 4. Computer(s) Yes[ ] No[ ] 5. Television Yes[ ] No[ ] 6. DVD/MP3Player Yes[]No[] 7. Electricity Yes[ ] No[ ] 8. Refrigerator Yes[ ] No[ ] 9. Electric iron Yes[ ] No[ ] 10. Washing machine Yes[ ] No[ ] 11. Internet access. Yes [ ] No[ ] 12. Telephone line Yes [ ] No[ ] 13. Radio Yes[ ] No[ ] 14. Deep freezer Yes[ ] No[ ] 15. Furniture Yes[ ] No[ ] 16. Dining table Yes[ ] No[ ] 17. Wall clock Yes[ ] No[ ] 18. Mobile phone Yes [ ] No [ ]	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18

15	Which of the following does your household use in cooking?	1. Fire wood [ ] 2. Straws [ ] 3. Cow dung [ ] 4. Charcoal [ ] 5. LPG [ ] 6. Electric cooker [ ] 7. Kerosene [ ] 8. No cooking is done [ ]	1 2 3 4 5 6 7 8
Section 2	Health Status		
1	Since when did you get diagnosed with diabetes?	…… year(s) ago	
2	What is your current blood glucose level averagely?	…… Mmol/L	
3	Do you have any other health problem?	1. Yes [ ] 2. No [ ]	1 2
4	If yes in the preceding question, then which of the following do you have?	1. Hypertension [ ] 2. Foot ulcer [ ] 3. Kidney disease [ ] 4. Eye problem [ ] 5. Boils [ ] 6. Depression [ ] 7. Prostate cancer [ ] 8. Numbness(neuropathy)[ ]	1 2 3 4 5 6 7 8
5	Who pay(s) for the diabetes care?	1. Myself [ ] 2. Spouse [ ] 3. Parents [ ] 4. Child/Children [ ] 5. NHIS [ ] 6. Private Insurance [ ] 7. Other Relatives (brothers, sisters, etc.) [ ]	1 2 3 4 5 6 7

6	If it is NHIS or Private Insurance that pays for your medical care; then is it all the bills or part?	1. Yes, full payment [ ] 2. Not full payment	1 2
7	If your answer to question 6 is 'Not full payment', what proportion do you estimate them to be paying?	1. Pays ≥ ¾ but <100% [ ] 2. Pays ≥1/2 but <3/4 [ ] 3. Pays ≥1/4 but <1/2 [ ] 4. Pays <1/4 but > 0 [ ]	1 2 3 4
Section 3	**Direct cost**		
	Direct medical cost		
1	How much do you spend on each of the following monthly?	GHC	
	Consultation	…….	
	Laboratory tests	……..	
	X – Ray	…….	
	Scans	……..	
	Oral medications	…….	
	Insulin	……..	
	Syringes and needles	…….	
	Wound dressing	…….	
2	How much do you spend on admission yearly?	GHC ……..	
3	How much do you spend on surgical procedures (Debridement, amputation, eye surgeries) yearly?	GHC ……	
	Direct nonmedical cost		
4	How much do you spend on the following monthly?	GHC	
	transportation to hospital for		

	treatment	GHC …….	
	Feeding yourself when you attend hospital	GHC……	
	Lorry fare and food for the caregiver	GHC…….	
	Others	GHC…….	
Section 4	**Indirect cost**		
1	How much time do you lose to due hospitalization; and how much does it translates to your earning per that time in a month?	…… days GHC …….	
2	How much time do you lose by visiting hospital for regular review; and how much does it translates to earnings if you were working	……..hours GHC ……	
3	How much time and earnings do you think your caregiver loses by accompanying you to the hospital (if applicable)	…….. hours GHC ……..	
4	Do you have disability due to diabetes?	1. Yes [ ] 2. No [ ]	1 2
5	If you have disability, then how much earning does it takes away from you?	GHC ……..	
6	Does family member under diabetes treatment affect household income?	1. Yes [ ] 2. No [ ]	1 2
7	Does the death of a diabetic in your household affect your	1. Yes [ ] 2. No [ ]	1 2

	finances?		
8	If yes for questions 6 & 7 under this section, then how much will that be in a month?	GHC …….	
Section 5	**Intangible cost**		
1	How much physical pain do you experience as a diabetic?	1. None [ ] 2. Mild [ ] 3. Moderate [ ] 4. Severe [ ] 5. So severe [ ]	1 2 3 4 5
2	How often is the pain?	1. Not at all [ ] 2. Occasionally [ ] 3. Often [ ] 4. Very often [ ] 5. Always [ ]	1 2 3 4 5
3	Does the pain prevent you from working at times?	1. Yes [ ] 2. No [ ]	1 2
4	If yes to question 3 under this section, then how often?	1. Not at all [ ] 2. Occasionally [ ] 3. Often [ ] 4. Very often [ ] 5. Always [ ]	1 2 3 4 5
5	How much time and productivity (earnings) do you think the pain could cost you?	…….. ….per month GHC ……..	
6	Do you often feel anxious, stressful & depressed due to psychological pain?	1. Yes [ ] 2. No [ ]	1 2
7	How often is this psychological	1. Always [ ]	1

	pain mentioned above?	2. Occasionally [ ] 3. Often [ ] 4. Very often [ ] 5. Always [ ]	2 3 4 5
8	Does this psychological pain prevent you from working?	1. Not at all [ ] 2. Occasionally [ ] 3. Often [ ] 4. Very often [ ] 5. Always [ ]	1 2 3 4 5
9	If this psychological pain prevent you from working effectively, then how much does it translate to your earnings?	GHC ……..	
10	Do you have any sexual weakness due to diabetes and its medications?	1. Yes [ ] 2. No [ ]	1 2
11	Do you have any problem with your marriage due to the sexual weakness mentioned above?	1. Not at all [ ] 2. Yes! Occasionally [ ] 3. Yes! Often [ ] 4. Yes! Very often [ ] 5. Yes! Always [ ]	1 2 3 4 5
12	If yes to question 11 under this section, then are you still:	1. Married with no problem[] 2. Married with few problems [ ] 3. Married with many problems[ ] 4. Separated [ ]	1 2 3

		5. divorced [ ]	
			4
			5
13	If you are separated or divorced, does it affect the household income?	1. Yes [ ] 2. No [ ]	1 2
14	If the divorce or separation do affect the household income, then how much is the effect?	1. No effect [ ] 2. Very little effect [ ] 3. Little effect [ ] 4. Much effect [ ] 5. So much effect [ ]	1 2 3 4 5

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

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

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax + 233-302-685424
Email: ghserc@gmail.com
24th May, 2018

MyRef. GHS/RDD/ERC/Admin/App 18/249
Your Ref. No.

Adam Joseph
University of Ghana
School of Public Health
Legon, Accra

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

GHS-ERC Number	**GHS-ERC075/01/18**
Project Title	Assessment of the Economic Burden of Diabetes Management/Treatment to Households in Denkyenbour District, Eastern Region, Ghana
Approval Date	24th May,2018
Expiry Date	23rd May, 2019
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

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

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

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

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

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

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