SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

QUALITY OF DIABETES CARE AT THE GREATER ACCRA REGIONAL HOSPITAL

BY

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

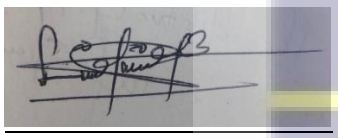
MAY 2023

DECLARATION

I, Delali Kwaku Letsa, declare that except for other works which have been duly acknowledged, this work is the result of my own original research, and that as far as I am aware, this dissertation, either in whole or in part, has not been presented elsewhere for another degree.

Dr. Delali Kwaku Letsa 19th May 2023.

(Student)



Dr. Leonard Baatiema 19th May, 2023.

(Academic Supervisor)

DEDICATION

This dissertation is dedicated to God Almighty for His provision and grace. Glory be to God on High!

This is also dedicated to my lovely wife, Ruth and amazing daughter Mikayla-Inez, for your support through every step of this journey.

ACKNOWLEDGEMENT

I first of all want to acknowledge the Almighty God for His grace and guidance throughout the program and its successful completion.

I also want to thank my supervisor, Dr. Leonard Baatiemah for his support and guidance. To my junior colleagues, especially Drs. Bernard Elorm-Ogbete and Enoch Osei Mensah, who volunteered to assist in data collection, I say a big thank you and God richly bless you.

Finally, I would also like to appreciate my family, for their endless support, prayers and encouragement throughout my program of study.

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ABBREVIATIONS

ACSC - Ambulatory Care Sensitive Condition

ADA – American Diabetes Association

BP – Blood pressure

CAD - Coronary Artery Disease

CKD – Chronic Kidney Disease

CVD - Cardiovascular Disease

DEMSoG - Diabetes Endocrine & Metabolic Society of Ghana

DFD – Diabetic Foot Disease

DM – Diabetes Mellitus

GARH – Greater Accra Regional Hospital

HBA1C - Glycated Haemoglobin

IDDM – Insulin Dependent Diabetes Mellitus

IDF – International Diabetes Federation

LDL - Low Density Lipoprotein

LMIC - Low-Middle Income Countries

NCDs – Non-Communicable Diseases

NDQIA - National Diabetes Quality Improvement Alliance

NHIA – National Health Insurance Authority

NHIS – National Health Insurance Scheme

NICE - National Institute of Clinical Excellence

OECD - Organization for Economic Co-operation and Development

OPD – Out-Patient Department

SARA - Service Availability and Readiness Assessment

SSA - Sub-Saharan Africa

STG - Standard Treatment Guidelines of Ghana

T1DM- Type 1 Diabetes Mellitus

T2DM – Type 2 Diabetes Mellitus

WHO – World Health Organization

ABSTRACT

Background: Diabetes mellitus (DM), which is on the rise globally at an alarming rate, is a significant and expensive public health concern that world leaders are focusing on for research and action. Despite the increased attention, questions have been raised over the standard of diabetes care, particularly in LMIC and the Sub-Saharan African region where diabetes care is still seen as substandard.

Method: This was a two-part study to assess the quality of Diabetes care at GARH. The structure and input domain was assessed using an adapted checklist from the WHO Service Availability and Readiness Assessment (SARA) tool. The process and outcome domains were assessed using a retrospective medical audit of attendants' medical records at the Greater Accra Regional Hospital's Diabetes Clinic utilizing the NDQIA selected indicators for process of care and outcome assessment. Descriptive statistics such as means, standard deviation, frequencies, and proportions were used to summarize continuous and categorical variables. Pearson's Chi-square test/Fisher's exact test (where appropriate) were used to examine the associations between the dependent variables (process of care indicators, outcome indicators; HBA1C, LDL, BP) and the independent variables (socio-demographic characteristics). P-values less than 0.05 were regarded as statistically significant.

Results: All assessed input indicators such as personnel, equipment, logistics etc. were present except for a dedicated nephrologist and podiatrist. The mean age of the clinic attendants was 60±12, with females accounting for a considerable majority (69.3%). Almost all the participants (n=180, 95.2%) were covered by the National Health Insurance Scheme. Two thirds of the patients (n=125, 66.1%) relied solely on oral hypoglycemic agents for their

glycemic control. There were significant shortcomings in HBA1C monitoring, LDL monitoring, foot examination, smoking status documentation, and microalbuminuria screening however all clients had their blood pressures monitored. Regarding clinical outcome assessment, the mean HBA1C of the attendants in this study who had a documented HBA1C level was 8.5%. Most attendees (n=110,58.2%) had blood pressure readings higher than 140/90 mmHg and only one-fifth of the patients had LDL levels of <2.6 mmol/l, with a mean LDL level of 2.8 mmol/l. All outcome indicators were above recommended targets for the diabetic population.

Conclusion: The study affirms previous literature that the quality of care of DM is subpar in LMICs. Although the structural/input domain of the assessment was almost adequately satisfied, efforts should be focused on promoting and ensuring optimal care processes and outcomes at the Greater Accra Regional Hospital and by extension other diabetes clinics across the country and subregion through a collaborative effort by all stakeholders.

CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes mellitus has had a significant global impact since the early 2000s, with a 70% increase in its contribution to global mortalities, warranting its inclusion in the top ten causes of death (WHO, 2020).

Regardless of the numerous interventions carried out by various institutions, the prevalence of diabetes with its associated morbidity and mortality continues to increase globally (IDF, 2017). In 2021, the International Diabetes Federation (IDF) reported that 537 million adults aged 20 to 79 worldwide had diabetes; this figure is projected to increase to 783 million adults in the same age range by 2045 (IDF, 2021). This projection postulates a 46 percent increase in the prevalence of diabetes as against the 20% increase in the world population estimated for the same period, with about 94% of the increase in diabetes prevalence by 2045 expected to occur in low- and middle-income countries (LMICs) due to a combination of factors, primarily lifestyle changes (IDF, 2021).

In the Sub-Saharan African (SSA) region, an estimated 15.5 (9.8-27.8) million were reported to be living with diabetes in 2017, with a regional prevalence of roughly 6% and related healthcare expenses of USD 3.3 billion (IDF, 2017). More recent studies in the region estimated a prevalence of 4.5%, with an expected increase of about 1.3 times in the number of people with diabetes by 2045 (IDF, 2021). This notwithstanding, it is reported that the prevalence of diabetes is anticipated to rise faster in SSA than in any other geographical region (Agyemang et al., 2016).

Similar to other LMICs, Ghana is also witnessing a major rise in the burden of diabetes. Based on a meta-analysis by Asamoah-boaheng et al. (2019), the findings showed that the prevalence

of diabetes mellitus among adult Ghanaians was estimated to be 6.46%, which was similar to other published community-based studies in Ghana as well as sub-regional estimates but was however found to be significantly higher than the Ashanti Regional estimate of 3.8% and national prevalence rate of 2.5% as estimated by the IDF in 2020 (Bawah et al., 2019; IDF, 2021; Katey et al., 2022). Past evidence has also revealed that between 0.077 and 6% of Ghanaians have been found to have diabetes, with prevalence rising with age and significantly higher in the urban areas compared to the rural areas (Amoah et al., 2002; Cook-Huynh et al., 2012; Danquah et al., 2012; Saeed et al., 2013).

A holistic view of the burden of diabetes in the SSA region would however require that the high proportion (53.6%) of undiagnosed diabetics be accounted for (IDF, 2021). Recent studies have reported that between 42-75% of diabetics worldwide are unaware of their diabetic status with almost 84% of all undiagnosed diabetics being found in low- and middle-income countries (Asmelash & Asmelash, 2019; Claypool et al., 2020; Fottrell et al., 2016)

In addition to the significant prevalence, the SSA region which is made up predominantly of low-middle income countries (LMIC) is riddled with the peculiar challenge of the 'double burden of disease' where diabetes not only increases the risk of developing severe infections in the region, such as tuberculosis, pneumonia and sepsis but also competes for the limited human and financial resources available (Beran & Yudkin, 2006; Eghan et al., 2007). The global expenditure on diabetes in 2021 was estimated to be 966 billion dollars, with an estimated 13 billion dollars spent on healthcare for people with diabetes in Africa alone (IDF, 2021). Considering that African countries are predominantly LMICs, concerns exist on how cost-effective this expenditure is, in terms of how it reflects in the quality of care.

Globally, the quality of diabetes care is variable but largely considered to be suboptimal in most countries; both high and low-middle-income countries (LMICs) but poorer in the LMICs

(Adeleye & Kuti, 2017; Fekadu et al., 2019; Flores-Hernández et al., 2015; Novo & Jokić, 2008; Pastakia et al., 2018). The Ghanaian context does not differ significantly from that of other LMICs and countries in the sub-region. Although no studies were found measuring them as a composite measure of the quality of care, studies evaluating individual outcome measures i.e., glycated haemoglobin, LDL and blood pressure levels among Ghanaian diabetic populations reported significant proportions of diabetics recording above recommended normal ranges of these biochemical and clinical measures (Adinortey et al., 2011; Danquah et al., 2012; Tagoe & Amo-Kodieh, 2013).

In terms of the complications of DM, macrovascular complications like strokes, peripheral vascular disease and cardiovascular diseases have been found to be more common among people living in High-Income Countries. This is contrasted by the high incidence rates of microvascular complications observed in most Low-Middle Income Countries especially the sub-Saharan African region, especially in those who have had a longer course of disease and poor glycemic control (Hall et al., 2011; Mwendwa et al., 2005; Pastakia et al., 2017). Good quality diabetes care evidenced by good outcome indicators has been proven to significantly delay or prevent the incidence of diabetic complications (IDF, 2017).

In order to ensure the early diagnosis, reduction in the incidence and progression of the aforementioned complications, in 2005, the then National Diabetes Quality Improvement Alliance (NDQIA) in the US now Diabetes Advocacy Alliance, identified nine priority diabetes care indicators; six process of care indicators and three proximal outcome indicators (NQDIA, 2005). These indicators were later adapted by the Organization for Economic Co-operation and Development (OECD) in 2006 for benchmarking the performance of member states' healthcare systems in regard to the diabetes care quality (Nicolucci et al., 2006). Many researchers have since reviewed, adapted, and utilized these indicators in assessing the

quality of diabetes care being offered at various levels of the healthcare system (Adeleye & Kuti, 2017; Calsbeek et al., 2013; Pastakia et al., 2018; Schneiders et al., 2019).

The goal of all stakeholders and healthcare providers involved in diabetes care has been and should remain the provision of optimal quality of care for all their clients. The optimum care of Diabetes is centered on balancing the short- and long-term effects of the disease and its treatment, ensuring improvement in patient health and well-being, and proactively stewarding healthcare resources for the benefit of both the patient and society (Rodriguez-gutierrez et al., 2020).

1.2 Problem Statement

The escalating global prevalence of diabetes mellitus (DM) has prompted significant attention from world leaders, acknowledging its importance as a costly public health issue (Chowdhury et al., 2022). Despite this heightened awareness, concerns persist, particularly in low- and middle-income countries (LMICs) and the Sub-Saharan African region, where the quality of diabetes care is often characterized as inadequate (Adeleye & Kuti, 2017; Fekadu et al., 2019; Flores-Hernández et al., 2015; Novo & Jokić, 2008; Pastakia et al., 2018). While recent studies in the subregion, including Ghana, have extensively delved into various facets of diabetes, such as prevalence, risk factors, and complications, there exists a notable research gap regarding the quality of diabetes care specifically evaluated through care indicators (Agyemang et al., 2016; Asamoah-boaheng et al., 2019; Bawah et al., 2019; Danquah et al., 2012; Katey et al., 2022; Saeed et al., 2013).

Recognizing diabetes as an ambulatory care sensitive condition (ACSC), the study emphasizes the potential impact of high-quality ambulatory care in reducing hospitalizations and complications, contrasting with inadequate primary care and substandard care, which may lead to avoidable complications and hospitalizations (Sarmento et al., 2020). Recent annual reports

from the Greater Accra Regional Hospital (GARH) reveal concerning trends in diabetes-related hospitalizations, particularly at the emergency department and among clients of the hospital's diabetic clinic. The rising prevalence of diabetic foot complications, a significant long-term consequence of poorly controlled diabetes, further accentuates the urgency of evaluating the quality of care at the outpatient diabetes clinic of GARH (GARH, 2021).

Existing evidence from prior studies highlights the importance of monitoring diabetic patient care using quality indicators to enhance disease management and reduce associated complications and treatment costs (Calsbeek et al., 2013; Nicolucci et al., 2006; Schneiders et al., 2019). Therefore, this study aims to address the identified research gap by assessing the quality of DM care, expecting to identify treatment gaps, specific care indicators requiring attention, and providing a benchmark for monitoring changes in quality over time. This comprehensive evaluation seeks to promote an optimal organizational-level standard of diabetes care, ultimately contributing to the reduction of undesirable health outcomes.

1.3 Justification of Study

This study is aimed at assessing the quality of DM care from a health system perspective, evaluating relevant input, process, and outcome measures. The findings from this study will benefit various levels of the healthcare system. The GARH as well as other Health care provider organizations can utilize the findings of this study to launch quality improvement initiatives to improve performance in the quality of diabetes care, improve health at the population level, narrow disparities in care and health outcomes and reduce costs of care by offering relevant targeted and customized affordable care to attendants at the DM Clinic. The clinicians can also use the data provided from this study to engage in relevant professional development and improvement efforts to address performance challenges with diabetes care quality. Lastly if a similar study is replicated across different facilities, findings could be

used by patients to select and monitor hospital and clinician performance with respect to diabetes care quality and also guide their selection of facility of preference in regard to their diabetes care.

1.4 Conceptual Framework

The conceptual framework below shows the interconnections between the sociodemographic characteristics of clients, their process indicators and proximal outcome indicators.

The age of a client may significantly influence health-seeking behavior as well as motivation for compliance and adherence to care provider recommendations and instructions thereby affecting their process and outcome measures, respectively. For instance, an elderly patient may have challenges with strict adherence to follow-up schedules (where the process measures are carried out) as compared to a younger patient as the former may require some assistance or company for clinic visits. They may also have challenges with instructions such as dietary restrictions as they most likely would be dependents or at least assisted in regard to meal choices and meal preparation. The effect of diet on the outcome measures are quite predictable.

Depending on the condition, health seeking behavior has been observed to differ across the sexes. It may be more likely for a Ghanaian woman to seek medical attention quickly as compared to her male counterpart because illness is still viewed by some men as a sign of weakness. Some signs of DM complications in men such as erectile dysfunction may be considered embarrassing and may influence clinic visits and adherence to treatment as the drugs may be viewed as the cause. This may affect outcome measures for which medications have been instituted.

Employment and income status will definitely affect the ability of clients to readily undergo required routine tests and imaging. Where there are financial challenges, finances may be directed towards treatment as against investigations intended to screen for complications.

Similarly insured clients may have better process measures because there will be little or no out-of-pocket expenditure, hence they may have funds to carry out relevant investigations. They may also be more likely to be compliant as the cost of hospital attendance will be subsidized by the insurer.

The treatment option being utilized may affect the outcome measures as some of the treatment options are known to produce more significant changes in the outcome measures if adhered to strictly. Also, how long a client has been diabetic can affect their compliance with treatment regimens, willingness to carry out routine tests and routine examinations. Some may also have developed some of the complications being assessed for and may be less interested in following through with recommendations.

Beside the possible effect of the sociodemographic factors on process and outcome variables, the presence of or adherence to relevant process measures may result in treatment intensification leading to better outcome measures. For instance, if an LDL test is carried out and found to be deranged at a follow up visit, statin therapy may be optimized leading to better control as against that of a patient with a similar LDL level but who was not tested at follow up hence had no optimization of medications done.

Poor outcome variables may also increase the occurrence of some process indicators; a deranged glycated haemoglobin will require a retest in three months which will lead to the fulfillment of the minimum requirement of annual HBA1C testing.

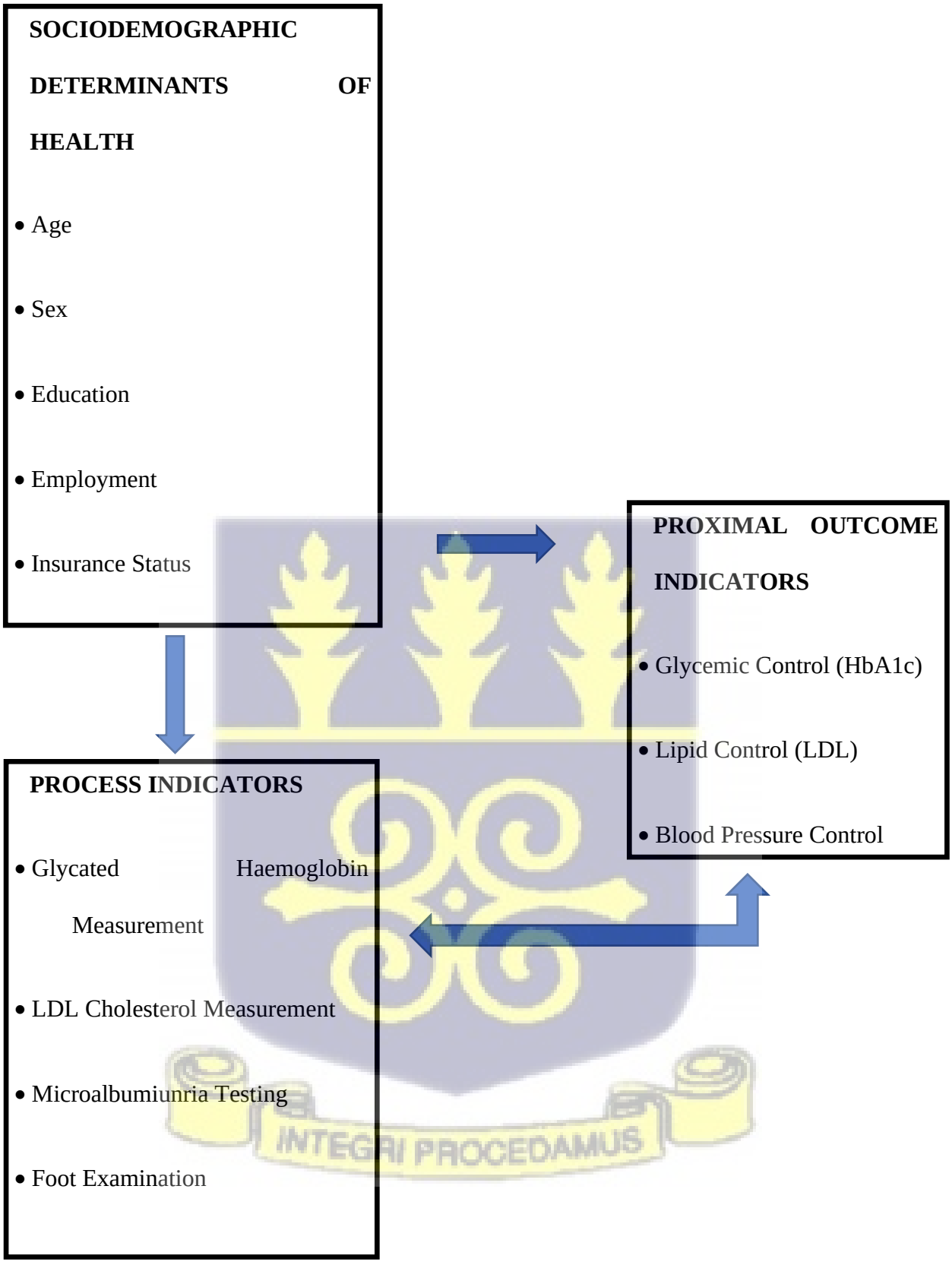

Figure 1. Conceptual framework: Relationship between sociodemographic characteristics, process indicators and outcome indicators

1.5 Research Questions

1. What are the available structures and clinical input measures present at the DM Clinic?
2. What proportion of attendants at the DM Clinic have good process indicators?
3. What proportion of attendants at the DM Clinic have good proximal outcome measures?
4. Is there an association between the sociodemographic factors and the quality care indicators of attendants at the DM Clinic?

1.6 Objectives of the Study

1.6.1 General Objective

To evaluate the quality of diabetes care provided at the Diabetes Clinic at GARH through a medical audit, by employing the quality indicators approved by the National Diabetes Quality Improvement Alliance (NDQIA) of the United States.

1.6.2 Specific Objectives

1. To assess the available structures and clinical input measures present at the DM Clinic.
2. To determine the proportion of clients, attendant at the DM Clinic who have good process indicators.
3. To determine the proportion of clients who have good proximal outcome measures.
4. To assess the association between the sociodemographic factors and the quality of care indicators of attendants at the DM Clinic.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter reviews literature on the subject matter and recent studies relevant to this study. The literature review is organized around the proposed objectives and research process of the study, and it is presented as follows:

2.2 Overview of Diabetes

The sections below review the most recent updates on diabetes under the headings most relevant to this study.

2.2.1 Definition

The International Diabetes Federation defines diabetes as a "a serious, chronic condition that occurs when the body cannot produce enough insulin or cannot effectively use the insulin it does produce" (IDF, 2021). The WHO definition emphasizes the metabolic nature of the disease and the deleterious effects of the elevated blood glucose levels on the heart, blood vessels, kidneys, eyes and nerves (WHO, 2020).

2.2.2 Pathophysiology and classification of Diabetes

The essential feature shared by all types of diabetes is the malfunction or loss of pancreatic beta-cells, which are responsible for the production of insulin. The most current classification of Diabetes used is based on the specific aetiopathogenesis of each subgroup and it is valuable in the clinical assessment of disease and for choosing appropriate therapy. This categorization divides diabetes into four major types, including Type 1 diabetes mellitus (T1DM), Type 2 diabetes mellitus (T2DM), Gestational diabetes mellitus (GDM), and diabetes brought on by or linked to a particular condition, pathology, and/or disorder (ADA, 2023). For the purposes of this study, only types 1 and 2 diabetes will be discussed.

Type 1 Diabetes Mellitus (T1DM), also known as type 1A DM has replaced the previous nomenclature of Insulin-dependent diabetes mellitus (IDDM) and juvenile-onset diabetes. It causes between 5 and 10% of all cases of diabetes. It is an autoimmune condition marked by the T-cell-mediated destruction of pancreatic beta-cells, which causes insulin deficiency and eventually, hyperglycemia (Kahaly & Hansen, 2016). Even though the pathogenesis of this autoimmunity is still not fully understood, it has been discovered that both hereditary and environmental variables play a role. The pancreatic beta-cell-specific autoimmunity and the disease itself develops at a rate that is typically as rapid as that of newborns and young children or as gradual as that of adults (Banday et al., 2020).

Type 2 Diabetes Mellitus (T2DM), also previously known as non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes accounts for about 90–95% of all the cases of diabetes. Although T2DM, in general shares similar symptoms with T1DM, symptoms are less severe and in most instances, majority of the individuals affected are asymptomatic (IDF, 2017).

Two main insulin-related pathologies characterize T2DM: insulin resistance and β-cell dysfunction (Muoio & Newgard, 2008). Insulin resistance is caused by malfunctions in several cellular pathways, which result in a decreased cellular response or sensitivity of cells in peripheral tissues (skeletal muscle, liver, and adipose tissue) to insulin. Reduced insulin sensitivity in the early stages of the disease causes enhanced beta-cell function, which results in an increase in insulin secretion as a compensatory mechanism to maintain normal blood glucose levels. Thus, hyperglycemia is prevented by the higher levels of circulating insulin (hyperinsulinemia). However, over time, the beta-cells' increased insulin secretion is unable to fully make up for the lowered insulin sensitivity. The function of the beta-cells then starts to deteriorate, which eventually causes insulin deficiency and subsequently hyperglycemia (Banday et al., 2020).

2.2.3 Diagnosis

The diagnosis of diabetes can be made based on either a random venous plasma glucose concentration ≥ 11.1 mmol/l in the presence of symptoms (such as polyuria, polydipsia, and unexplained weight loss), or in the absence of symptoms by fasting (no calorie intake for at least 8 hours) plasma glucose concentration ≥ 7.0 mmol/l (whole blood ≥ 6.1 mmol/l or HbA1c ≥ 6.5%).

Repeat testing, ideally with the same test, is advised as soon as is practicable on the following day to confirm the diagnosis if elevated results are found in asymptomatic individuals (Chawla et al., 2020; IDF, 2017).

2.2.4 Principles of Management

The principal goals of diabetes management are to prevent its complications and to optimize the quality of life of diabetic patients (ADA, 2023). The most current "Standards of Care in Diabetes -2023" recommendations by the ADA, recommend among others the following in achieving the overall goals of good quality diabetes care; 1. Early detection and monitoring of pre-diabetics and at-risk populations like the obese and clients managed previously for Gestational Diabetes, 2. Intense lifestyle modifications for all diabetics and high-risk groups, 3. Setting of person-centered goals with adequate risk stratification and prompt initiation of pharmacotherapy where indicated, 4. Screening for and prevention of vascular complications and mortality.

2.2.5 Treatment Modalities for Diabetes

Treatment modalities for diabetes have remained fairly constant since the 1980's with varying emphasis on different modalities in a client-specific manner. The aim of both ancient and current modalities has been to control blood glucose levels within normal ranges for a given population (Canpolat & Şahin, 2021; Lawrence & Abraira, 1988).

Specific modalities used in achieving this treatment goal include lifestyle modification, oral antidiabetic drugs and insulin injections, usually implemented in sequence from prediabetes to diabetes with complications. Other medications are most often added to control blood pressure, dyslipidemia and other disorders, since patients often have multiple chronic conditions (GarcíaPérez et al., 2013).

2.2.6 Complications

Diabetic complications can pose a significant challenge to the quality of life of Diabetics. Vascular complications are the most detrimental. It is subdivided into macrovascular and microvascular complications. Macrovascular complications include peripheral artery disease, myocardial infarction, coronary heart disease, and stroke. It is worth noting that diabetes is not a prerequisite for developing macrovascular complications. Microvascular complications on the other hand include diabetic nephropathy, neuropathy, and retinopathy (Chawla et al., 2016).

When compared to the general population without diabetes, diabetics have been found to have a 2–4-fold higher risk of developing coronary events and cardiovascular mortality (Dal Canto et al., 2019; Paneni et al., 2013). Although studies have identified biological mechanisms linked to DM that independently raise the risk of cardiovascular disease (CVD) in diabetic patients, the prevalence of cardiovascular risk factors among patients with DM, such as obesity, hypertension, and dyslipidemia, raises the population's risk for severe adverse cardiovascular events (Leon, 2015).

Recent studies have reported a decline in vascular complications worldwide but with an increase in Diabetic vascular complication-related deaths (Ling et al., 2020). It is noteworthy that many undiagnosed diabetics present with complications already at diagnosis (Asmelash & Asmelash, 2019).

2.2.6.1 Coronary Heart Disease

Patients with diabetes are more likely to develop atherosclerosis and its clinical consequences, especially coronary artery disease (CAD). One of the leading causes of death for diabetic patients continues to be CAD. Numerous factors, including hyperglycemia, insulin resistance, abnormal lipid profiles, oxidative modification of lipoproteins, elevated blood pressure, altered rate of fibrinolysis, etc., speed up the pathophysiological process of atherosclerosis in diabetic subjects. These modifications in people with diabetes make the dormant atherosclerotic plaque susceptible, which can lead to an early clinical event like a myocardial infarction (Arvind et al., 2002).

After adjusting for other risk variables, diabetes was found to be related to an approximately two-fold higher risk of CHD in a meta-analysis encompassing about 700 000 people from 102 prospective studies (Sarwar et al., 2010).

2.2.6.2 Stroke

A well-known risk factor for stroke is diabetes. When blood vessels in different parts of the body are altered by the persistent hyperglycemia's pathologic processes, stroke may result if cerebral vessels are specifically affected. Even after a stroke event, mortality is higher and poststroke outcomes are worse in the absence of proper monitoring and control of the condition. Controlling diabetes and other risk factors like hypertension, atherosclerosis, smoking, and atrial fibrillation is a good strategy to stop diabetics from experiencing an initial stroke as well as preventing strokes from recurring (Ling et al., 2020; Putaala et al., 2011).

2.2.6.3 Diabetic Foot Disease

Diabetes-related peripheral neuropathy (damage to peripheral and autonomic nerves) and peripheral arterial disease (disease that changes the normal bodily response to wound healing) are the two main diseases that make up diabetic foot syndrome or disease (DFD),

which leads to foot ulceration. Foot ulcerations can eventually require amputation if they are not treated appropriately or are detected and treated late, particularly when infections are present (Amin & Doupis, 2016). This debilitating condition affects almost half of the diabetic population with varying severity and attendant morbidity (Tong et al., 2006).

Noteworthy risk factors include smoking, advanced age, duration since diagnosis, hypertension, and dyslipidemia. Others include foot deformity, diabetic foot ulceration or a history of lower limb amputation (Criqui & Aboyans, 2015).

2.2.6.4 Diabetic Retinopathy

Diabetic retinopathy (DR) is a leading cause of blindness worldwide, with approximately one-third of all diabetics showing indications of DR, of which one-third have vision-threatening DR, including diabetic macular edema (DME). The diagnosis of DR is based on examining the retina usually carried out by a trained healthcare professional and treatment is based on disease severity and classification (Wu et al., 2013). The most major risk factors for progression to visual loss are diabetes duration, hyperglycemia, and hypertension (Lee et al., 2015).

2.2.6.5 Diabetic Nephropathy

Chronic Kidney Disease (CKD) is defined as kidney damage or a glomerular filtration rate (GFR) of <60 mL/min/1.73m² for 3 months or more, regardless of etiology. Kidney damage is established in most kidney diseases, including diabetic nephropathy, by the presence of albuminuria, defined as an albumin-to-creatinine ratio of more than 30 mg/g in two of three spot urine specimens (Levey et al., 2005)

The most frequent cause of chronic kidney disease among diabetics is diabetic nephropathy, which is characterized by hypertension, increasing albuminuria, glomerulosclerosis, and falling eGFR. Age, sex, predisposing genes, hyperglycemia, hypertension, smoking,

dyslipidemia, and insulin have all been identified as risk factors for diabetic nephropathy. Individuals with type 1 diabetes have a higher risk of CKD than those with type 2 diabetes. Hypertension frequently precedes kidney disease in type 2 diabetes, and hypertension contributes to the progression of kidney disease from diabetic nephropathy (Van Buren & Toto, 2011).

2.3 Quality of Diabetes Care

The quality of diabetes care is a comprehensive and multifaceted concept, encapsulating various dimensions such as effectiveness, accessibility, safety, patient-centeredness, timeliness, and equity within diabetes care services (Zhang et al., 2020). Measuring and monitoring the quality of diabetes care is essential for identifying areas that require improvement and developing effective strategies to enhance patient outcomes (Agyemang et al., 2023). However, it is noteworthy that there is no universally accepted definition or standardized set of parameters for assessing the quality of diabetes care. Different institutions employ distinct criteria to measure and evaluate the quality of diabetes care, reflecting the varied perspectives and priorities in healthcare settings. This diversity in assessment criteria underscores the complexity of defining and gauging the quality of diabetes care across different healthcare contexts.

Measures of quality of diabetes care can be categorized into three main groups: structure, process, and outcome (Wang et al., 2022). Structural measures assess the resources and infrastructure that support diabetes care, such as the availability of qualified healthcare providers, access to diagnostic tests and medications, and the use of electronic health records (Egede et al., 2020). Process measures evaluate the activities and procedures that are involved in providing diabetes care, such as the frequency of patient visits, the documentation of key clinical information, and the provision of patient education and self-management support (Donelly et al., 2009). Outcome measures assess the patient's health

status and quality of life, such as glycemic control, blood pressure management, cholesterol management, and the prevention of diabetes complications (Hales et al., 2012).

By assessing quality of diabetes care across these dimensions and using appropriate measures, healthcare providers, policymakers, and researchers can identify critical gaps in care and develop targeted interventions to improve diabetes management and outcomes (Egede et al., 2020; Donnelly et al., 2009; Hales et al., 2012). This comprehensive approach to quality assessment can play a pivotal role in addressing the global burden of diabetes and ensuring that all individuals have access to high-quality diabetes care services.

In terms of structure process, research highlights the connection between comprehensive infrastructure and enhanced diabetes care (Agarwal, 2022; International Diabetes Federation, 2022). In North America, access to specialists, well-equipped clinics, and the incorporation of technology contribute to an elevated standard of service, ultimately positively influencing patient outcomes (Kline & Bennett, 2022; Wang et al., 2023). Similarly, Europe's commitment to standardized care protocols and investments in healthcare infrastructure yields a high level of service quality (European Diabetes Working Group, 2021). The implementation of evidence-based guidelines ensures consistent care delivery across regions, underscoring the pivotal role of well-established infrastructure in fostering quality diabetes care (Jenkins et al., 2022). Conversely, certain regions encounter challenges in infrastructure, affecting service quality. Latin American countries, actively striving to enhance healthcare infrastructure, grapple with disparities in service accessibility, impeding the consistent delivery of high-quality diabetes care (Barroso et al., 2022). These disparities hinder access to essential services and specialized care, contributing to suboptimal patient outcomes (Pereira et al., 2022).

In the realm of diabetes care processes, Europe's emphasis on standardized care protocols highlights the importance of a systematic approach (International Diabetes Federation, 2022;

European Diabetes Working Group, 2021). The implementation of these guidelines contributes to favorable outcomes, emphasizing the significance of adhering to established processes (Jenkins et al., 2022). In Asia, where healthcare systems exhibit wide variability, a trend towards personalized approaches to diabetes management is observed (Agarwal, 2022; Wang et al., 2023). Tailoring care to individual needs is viewed as a strategy to navigate the diverse healthcare landscape, indicating a shift towards patient-centered care processes (Pereira et al., 2022). The integration of technology into the care process is a global phenomenon, with North America, Europe, and parts of Asia adopting telehealth interventions (Kline & Bennett, 2022)

When evaluating diabetes outcomes, developed regions consistently demonstrate positive results (International Diabetes Federation, 2022; European Diabetes Working Group, 2021). Europe's commitment to standardized care, coupled with advanced infrastructure, leads to improved glycemic control and reduced complications, establishing a direct correlation between process adherence and positive outcomes (Jenkins et al., 2022). In the Middle East, despite cultural challenges, positive outcomes are emerging (Agarwal, 2022; Wang et al., 2023). The region's focus on targeted interventions has contributed to enhancements in glycemic control and patient well-being, underscoring the importance of culturally sensitive care approaches (Pereira et al., 2022). However, regions facing resource constraints encounter difficulties in achieving optimal outcomes (Kline & Bennett, 2022; Barros et al., 2022). Parts of Asia and Latin America, along with the majority of sub-Saharan Africa, while making progress in diabetes care, experience suboptimal outcomes due to limited access to medications, monitoring devices, and specialized care (Pereira et al., 2022).

Studies done in the Ghana and the subregion revealed suboptimal results in the assessment of the clinical indicators of the quality of DM care (Ababio et al., 2017; Adeleye & Kuti, 2017) when compared to recommended guidelines set by the ADA, NICE and studies in

developed countries. Studies done in Ghana assessed isolated outcome variables and the determinants of developing DM (Agyemang et al., 2016; Asamoah-boaheng et al., 2019; Bawah et al., 2019; Danquah et al., 2012; Katey et al., 2022; Saeed et al., 2013). These studies identified a high prevalence of diabetes among Ghanaians compared to the global rate. The studies further revealed that obesity, hypertension, physical inactivity and hyperlipidemia were associated with the development of diabetes mellitus and subsequently its complications among Ghanaians.

2.4 Quality of Diabetes Care Indicators

In 2005, the then National Diabetes Quality Improvement Alliance (NDQIA) of the US now Diabetes Advocacy Alliance, identified nine priority diabetes care indicators; six process of care indicators and three proximal outcome indicators (NQDIA, 2005). These indicators were later adapted by the Organization for Economic and Co-operation Development (OECD) in 2006 for benchmarking the performance of member states' healthcare systems in regard to diabetes care quality (Nicolucci et al., 2006). Many researchers have since reviewed, adapted and utilized these indicators in assessing the quality of diabetes care being offered at various levels of the healthcare system (Adeleye & Kuti, 2017; Calsbeek et al., 2013; Pastakia et al., 2018; Schneiders et al., 2019)

Recent authors have, however, made some recommendations for the review of these indicators to include additional diabetes care measures that, in their opinion, may better represent the outcomes that are truly important to people with diabetes, such as immediate symptoms of hypoglycemia or hyperglycemia, treatment burden, quality of life, and long-term consequences of inadequately controlled diabetes (Jiang et al., 2022; Rodriguez-gutierrez et al., 2020). However, a consensus is yet to be drawn by relevant bodies.

Process of care measures focus on activities that reflect evidence-based care processes to maintain or improve health (such as completion of retinopathy screening, documentation of

smoking status) whiles outcome measures are surrogate outcome measures (such as haemoglobin A1c, blood pressure, and low-density lipoprotein cholesterol levels), which are clinical parameters that capture aspects of patients' health status and reflect risk for developing complications of diabetes (Jiang et al., 2022). Common complications or hard outcomes of diabetes include End-stage kidney disease, blindness, amputation, atherosclerotic cardiovascular disease events, and death. The early identification of these complications serves as the backbone for selected indicators.

According to Calsbeek et. Al (2013), the most frequently used quality indicators in the 86 studies examined were the following process measures: cholesterol measurement, blood glucose measurement, eye examination, urine testing, foot examination, blood pressure measurement, counseling on lifestyle and self-management (process), and blood glucose outcome, cholesterol outcome, and blood pressure outcome.

2.5 Diabetes Care Guidelines

The Standard Treatment Guidelines of Ghana (STG), published by the Ministry of Health of Ghana, is the ministry's officially recognized prescribers' and dispensers' guidance for all levels of healthcare. In the lack of a single set of standards for diabetes management, most practitioners rely on STGs and guidelines from international organizations such as the American Diabetes Association (ADA) and the National Institute of Health and Care Excellence (NICE) of the United Kingdom.

The Diabetes, Endocrine & Metabolic Society of Ghana (DEMSoG) which was established on the 25th October 2018 is currently working on national guidelines for the management of diabetes.

The following are the treatment objectives as specified by the most recent edition (7th Edition) of the Ghanaian STGs.

- To alleviate symptoms
- To avoid acute hyperglycemic consequences (such as ketoacidosis and hyperosmolarity)
- To avoid treatment-related hypoglycemia
- Achieving and maintaining adequate glycemic goals

o Fasting blood glucose levels of 4-7 mmol/L (lower glycemic goals in the elderly)

o 2-hour post-meal blood glucose of 5-9 mmol/L (in older patients, less intensive glycemic objectives)

o Glycated haemoglobin of 7% or below (in older patients, less intensive glycemic objectives)

- To ensure weight reduction in overweight and obese individuals
- To prevent chronic complications of diabetes by maintaining
    - The glycaemic targets stated above
    - Blood pressure less than 130/80 mmHg
    - LDL-cholesterol less than 2.5 mmol/L

CHAPTER 3

METHODOLOGY

Introduction

3.1 Study Design

A cross-section study design was employed first through a retrospective medical audit of attendants' medical records at the Greater Accra Regional Hospital's Diabetes Clinic. This clinical audit was done, using indicators for the process of care and outcome assessment established by the National Diabetes Quality Improvement Alliance (NDQIA). The second arm of the study utilized a checklist adapted from the WHO Service Availability and Readiness Assessment (SARA) tool to assess the structure and services available at the clinic and hospital at large.

3.2 Study Site

This study was conducted at the Greater Accra Regional Hospital (GARH), which is located in North Ridge in the Osu-Klottey Municipality of the Greater Accra Region (GAR) of Ghana. Its total land area is roughly 15.65 acres. The hospital serves as the Greater Accra regional hospital. The region has an estimated population of over 4,671,363 (2016 forecast based on the Ghana Statistical Service's 2010 census). Ridge, Nima, Maamobi, Kanda, Accra New Town, Kotobabi, Osu, La, Adabraka, Achimota, Airport Residential Area, and Central Accra are among the suburbs that are immediately within the catchment area.

The GARH, which is in the center of Accra, was founded in 1928 as a hospital for European expatriates. After Ghana's independence in 1957, it became a district hospital. In 1997, it was given the name Ridge Regional Hospital. In 2017, the hospital underwent extensive renovations to become an ultra-modern facility with 420 beds and a full range of specialized

services that reflects the aspirations of the country's capital, Accra, which is rapidly expanding.

It has a diabetic clinic that opened around 7 years ago and sees about 1500 patients a year. The diabetes clinic is scheduled for Tuesdays every week at the main OPD of the hospital. The main OPD has a waiting area with a current capacity of 120 and four consulting rooms allocated. There is a designated out-patient department laboratory adjacent to the waiting area. The eye clinic, dietician office and physiotherapy unit are all in the same building at the OPD.

All other NCDs such as hypertension are managed at the daily physician clinics run at the main OPD.

3.3 Study Population

The study population comprised medical records of clients diagnosed with Diabetes Mellitus and attendant at GARH DM Clinic between June 2021 and June 2022. Approximately 180 records will be reviewed.

3.3.1 Inclusion Criteria

Clients who attended the GARH DM clinic more than once within the 12-month period under review were eligible for the study.

3.3.2 Exclusion Criteria

Pregnant clients and clients with other endocrine conditions causing diabetes or which could complicate the management of diabetes were excluded.

3.4 Sample Size

The sample size was calculated using the Cochran's formula for categorical data. Proportions for each indicator from a similar study done by Adeleye & Kuti in 2017 in Ibadan, Nigeria were used to calculate sample sizes and the largest sample size chosen.

n=(〖(Z〗 _(∂/2))²p(1-p))/d^2 (Cochran,1963)

Sample size = **171 rounded to 180**

where:

n: sample size,

d: absolute error, 6% and

Z1-α/2=1.96 since α=5% at 95% CI.

P :0.799

3.5 Sampling Procedure

A systematic random sampling method was used to identify participant medical records. All folder numbers of attendants who visited the clinic within the period under review were arranged in numeric order constituting the sampling frame. The total population from the sampling frame was divided by the sample size calculated above to provide the sampling interval (k). A random starting point between 1 and k was chosen and then every kth folder number was chosen and assessed for inclusion or exclusion from the study. This process was repeated throughout the data collection process until the desired sample size was obtained.

3.6 Data Collection Tools and Procedure

Data collection was done via a pre-tested data abstraction tool designed by the researcher. The data abstraction tool was in three sections, including sociodemographic characteristics, indicators for process of care and outcome indicators for diabetes care assessment as selected by the National Diabetes Quality Improvement Alliance (NDQIA).

A checklist will also be administered to a key informant (Head of Clinic) to assess the structures and services available at the clinic. The selection of the key informant to fulfill the checklist will be carried out through purposive sampling and it is based on the key informant's

relevance to the checklist criteria. This strategic selection allows for a comprehensive assessment of the clinic's structures and services, as the key informant possesses in-depth knowledge and insights into the operations of the clinic. The checklist will be adapted from the tool used by Chowdhury et al. (2022) during a nationwide survey in Bangladesh for Service Availability and Readiness Assessment for Diabetes, the WHO Service Availability and Readiness Assessment Tool and using the WHO Framework for Health Systems as a guide.

3.7 Data Processing

3.7.1 Quality control

Prior to the actual data collection, research assistants were given prior training on the aims and purpose of the study, the data abstraction procedure and ethical guidelines as recommended by the Ethics Review Committee.

The data abstraction tool was first pretested on a 5% sample size at the family medicine department (Main OPD) of the GARH. The pre-testing of the data collection tool helped identify gaps in the data abstraction tool and procedure for necessary modifications and corrections. It also allowed research assistants to familiarise themselves with the data collection tools and instruments.

3.7.2 Statistical analysis

After data collection, data was entered using Microsoft Excel 2021 and then exported to Stata MP 17.0 for analysis. Descriptive statistics like means, standard deviation, frequencies and proportions were used to summarize continuous and categorical variables. A univariate analysis of background characteristics was conducted and reported in numbers and percentages. Pearson's Chi-square test/Fisher's exact test (where applicable) was used to determine association between the dependent variable (process of care indicators, outcome

indicators) classified into categorical data and the independent variables (socio-demographic characteristics). P-values less than 0.05 were considered statistically significant.

Information from the checklist was appropriately summarized and presented in tables where applicable.

3.8 Ethical Consideration

This study protocol with approval reference; GHS-ERC 027/04/23 was submitted to Ghana Heath Service Ethics Review Committee for ethical clearance. Additional permission was sought from the management and research department of the GARH to grant access to the medical records.

Data collected was kept under lock and key, with only the principal investigator having access. Online files were passworded to limit access to only the principal investigator.

To ensure anonymity, no patient-identifiable information was used. Sampled medical records were only identified with codes and numbers rather than folder numbers to further ensure anonymity after data collection.

The anonymity of the key informant for the service checklist was ensured.

3.8.1 Voluntary Participation and Right to Leave the Research

A key informant was identified to help complete the checklist administered by the primary investigator mentioned.

Although permission was sought from the head of the facility and other relevant authorities, participation in this study was voluntary and the right to withdraw from the study during the data collection process was maintained. There was no penalty for withdrawing from the study, and any information obtained from the individual was destroyed with subsequent identification of another key informant as per the hospital leadership's recommendation.

Consent to participate in this study required a signature or thumbprint on the consent form and a copy given to the participant.

Due the use of secondary data audit part of this study, voluntary participation and right to leave research was not applicable for the medical audit part of the study

3.8.2 Rights as a participant

The key informant had the right to withdraw from the study at any time. They were given a copy of the participant information sheet and signed consent form

Medical records of clients who have issued prior instructions against the use of their medical records in facility-based studies were exempted from the study

3.8.3 Informed consent

Two written informed consents were obtained from the key informant before enrolling in the study; a copy each for the principal investigator and key informant.

3.8.4 Confidentiality

Information obtained from the key informant and medical records was kept confidential. Identifying and personal information were anonymized during data entry, analysis, and dissemination of findings from the study. Codes were used during data management to avoid exposing the details of sampled medical records. Any data and information generated from participants was stored in an encrypted file accessible by the principal investigator.

3.8.5 Risks

There were no anticipated risks associated with this study. Information gathered from this study was purely for academic purposes. All information collected was stored securely, and accessible only by study staff. If information from this study is published or presented at

scientific meetings, personal identifiers will not be used. All participants' data will be kept for five years; after which time it will be destroyed.

3.8.6 Benefits

There was no direct benefit of this research to the study participants. However, it is anticipated that recommendations from this study aimed at improving diabetes care at the GARH will help improve individual health outcomes of all attendants at the clinic.

3.8.7 Compensation

There was no compensation for being a participant in this study. The study was for academic purposes, it was self-funded by the Principal Investigator and participant contributions were solely voluntary with minimal vulnerability of participants.

CHAPTER 4

RESULTS

4.1 Service Availability and Diabetes Clinical Input Indicators

The Diabetes clinic is a weekly clinic run with amenities available to all other clinics in the Out-Patient Department of the Hospital. The clinic which utilizes four shared consulting rooms, runs for about seven to eight hours and attends to approximately forty to fifty clients a day. The clinic is headed by a Senior Endocrinologist and Diabetologist who also happens to be the head of the department of Internal Medicine. The clinic caters for clients who either pay out of pocket, are insured by the National Health Insurance Scheme, private insurance schemes or by company health insurance schemes. The staff strength of the clinic is twenty, consisting of different cadres as summarized in table 1 below. The clinic has no dedicated nephrologist or podiatrist.

Table 1. Cadres of Health Workers at the Diabetes Clinic

Health Workforce	Staff Strength
Endocrinologists / Diabetologists	2
Ophthalmologist	1
Physician Specialists	1
Resident Physicians	3
Medical Officers	1
House Officers	4
Nurse Educators	1
Nurses	5
Dieticians	2

The physicians in the team receive an annual organized training session carried out by the department of Internal Medicine. The readily available equipment at the clinic include five measuring tapes, three sphygmomanometers, three thermometers, two adult weighing scales, a stadiometer and a pack of microfilaments. Laboratory services available in the OPD readily provide testing for blood glucose, urinalysis, glycated haemoglobin, lipid profile. The pharmacy is reported to stock the essential medicines for diabetes management. The Ghana Standard Treatment Guidelines is the most readily available evidence based guideline in the clinic.

4.2 Demographics

The total number of medical records audited for the study was 189. The mean age of the participants was 60.86, SD = 12.17. The modal age was 60, minimum age was 24 and maximum age was 91 (range = 67). The majority of the participants were 60 years or older (n=111, 58.7%). More than two-thirds (n=131, 69.3%) of the records reviewed belonged to females. Almost all the participants were insured under the National Health Insurance Scheme (n=180, 95.2%), one participant was privately insured, and the rest did out-of-pocket payment of their medical bills. The informal sector employed more than three-fourths of the participants (n=148, or 78.3%). Seventy-two (72) out of the 189 records reviewed (38.1%) had no documentation of the duration of their diabetes mellitus. The majority of participants (n=125, 66.1%) used oral hypoglycemic medications alone to control their blood sugar levels, whereas 28.6% of individuals (n=54) needed to use both oral hypoglycemic medications and insulin to do so. The demographic details of the participants are shown in Table 2.

Table 2. Sociodemographic characteristics of the participants

Sociodemographic characteristics	Frequency (n)	Percentage (%)
Age of participants		
<30	4	2.1
30 - 59	74	39.2
60 and above	111	58.7
Sex		
Males	58	30.7
Females	131	69.3
Insurance		
NHIS	180	95.2
Non insured	8	4.2
Private insurance	1	0.5
Employment sector		
Formal sector	41	21.7
Informal sector	148	78.3
Duration of DM		
1-5 years	45	23.8
6-10 years	93	14.8
Above 10 years	44	23.3
Not documented (ND)	72	38.1
Modality of treatment		
Oral hypoglycemics	125	66.1
Insulin	10	5.3
Both	54	28.6

4.3 Diabetes Quality of Care Clinical Process Indicators

A little less than one-fourth of the participants (n=41, 21.7%) never had their HBA1C levels assessed, whereas majority (n=148, 78.3%) had done so at least once. Approximately half of the population (n=97, 51.3%) had their LDL levels monitored at least once within the year under review. Majority of the participants (n=125, 66.1%) also had their eyes examined at some point within the year, however only half (n=95, 50.3%) had their feet examined and had their smoking status documented (n=96, 50.8%). Three-fifths of the participants (n=113, 59.8%) had been recommended for consultation with a dietician or nutritionist. One hundred and fifty-four (154, or 81.5%) of the individuals have never had a microalbuminuria test done or requested.

The process most carried out was HBAIC testing and the least performed process of care indicator was the test for microalbuminuria.

The clinical process indicators for the participants are shown in Table 3.

Table 3: Clinical process indicators of the participants

Indicator	Frequency (n)	Percentage (%)
HBA1C measurement		
None	41	21.7
At least once	148	78.3
LDL monitoring		
None	92	48.7
At least once	97	51.3
Eye examination referral		
Done	125	66.1
Not done	64	33.9
Foot Examination		
Done	94	49.7
Not done	95	50.3
Lifestyle modification		
Done	151	79.9
None	38	20.1
Smoking status documentation		
Done	96	50.8
Not Done	93	49.2
Test for microalbuminuria		
Yes	35	18.5
No	154	81.5

4.4 Diabetes Clinical Outcome Indicators

As illustrated by table 4, about a third (n=55, 29.1%) of the participants had achieved an HBA1C level less than 7.0%. The mean HBA1C of the attendants with a documented HBA1C level in this study was 8.5%. Majority of the participants had a BP measurement >140/90 mmHg (n=110,58.2%) with the mean BP being 142 ± 21/81.74 ± 11. Just about 1 in 5 of the participants had an LDL <2.6 mmol/l. The mean LDL level of the participants was 2.8 mmol/l.

Table 4: Clinical outcome indicators of the participants

Indicator	Frequency (n)	Percentage (%)
Most recent HBA1C		
<7.0%	55	29.1
7.0-9.9%	82	43.4
≥10%	42	22.2
Not documented (ND)	10	5.3
BP control (mmHg)		
<140/90 mmHg	79	41.8
>140/90 mmHg	110	58.2
Most recent LDL level (mmol/l)		
<2.6	38	20.1
2.6-3.3	59	31.2
>3.3	37	19.6
Not documented (ND)	55	29.1

4.5 Association between Sociodemographic Characteristics and Diabetes Quality of Care Process Indicators

Table 5. Association between sociodemographic characteristics and Diabetes quality of care clinical process indicators

Sociodemographic characteristics	HBA1C measurement	LDL monitoring	Eye examination	Foot Examination	Lifestyle modification	Smoking status documentation	Test for microalbuminuria
Age	0.388	0.519	0.292	0.051	0.352	0.282	0.321
<30							
30 - 59							
60 and above							
Sex	0.347[a]	0.059[a]	**<0.01[a]**	**0.007[a]**	0.078[a]	0.086[a]	0.224
Males							
Females							
Insurance	0.054	0.499	0.171	0.468	0.755	0.484	0.804
NHIS							
Non Insured							
Private insurance							

Employment sector	0.523[a]	**0.008[a]**	0.150[a]	0.158[a]	0.189[a]	0.293[a]	0.067[a]
Formal sector							
Informal sector							
Duration of DM	0.055	0.113	0.631	0.516	0.346	**0.022**	0.780
1-5 years							
6-10 years							
Above 10 years							
Not documented (ND)							
Modality of treatment	0.088	0.300	0.197	0.319	0.255	0.697	0.197
Oral hypoglycemics							
Insulin							
Both							

[a] for Fischer's exact test p-value. All other p-values are from Chi-square. (p-value significant at <0.05)

4.6 Association between Sociodemographic Characteristics and Diabetes Quality of Care Clinical Outcome Indicators

Table 6. Association between sociodemographic characteristics and Diabetes quality of care clinical outcome indicators

Sociodemographic characteristics	Most recent HBA1C	BP control	LDL levels
AGE	**<0.01**	**<0.01**	0.220
<30			
30 - 59			
60 and above			
SEX	0.545	**0.007[a]**	0.440
Males			
Females			
INSURANCE	0.597	0.439	0.855
NHIS			
Non insured			
Private insurance or company cover			
Employment sector	0.612	**0.020[a]**	**0.041**

Formal sector			
Informal sector			
Duration of DM	**<0.001**	**0.008**	0.319
1-5 years			
6-10 years			
Above 10 years			
Not determined (ND)			
Modality of treatment	**<0.001**	0.644	**<0.001**
Oral hypoglycemics			
Insulin			
Both			

[a] for Fischer's exact test p-value. All other p-values are from Chi-square. (p-value significant at <0.05)

CHAPTER 5

DISCUSSION

5.1 Introduction

This chapter discusses the results of the study considering the objectives proposed for the research. It also deals with how the results relate to and compare with other relevant literature.

5.2 Structural / Input Indicators, Service Availability and Readiness

According to Nuche-Berenguer & Kupfer (2018), the capacity for hospitals within Sub-Saharan African countries to manage diabetes is at the infancy level. Although Ridge hospital has an adequate number of medical staff to see clients a day, the hospital does not have a dedicated nephrologist or podiatrist. This makes the readiness of the hospital's healthcare system to provide quality diabetic care suboptimal. Similar suboptimal findings were reported in Malawi (Lutala et al., 2023) and Ethiopia (Bekele et al., 2017) and from a cross-country study in Afghanistan, Bangladesh and Nepal (Huda et al., 2021). These countries, like Ghana, have a high prevalence rate of diabetes mellitus. In a nationwide survey conducted in Bangladesh by Chowdhury et al., (2022), it was noticed that only tertiary hospitals are prepared enough to manage DM. Although the Greater Accra Regional Hospital is not a tertiary hospital, it operates as one, hence the quality of DM care is expected to be optimal.

5.3 Sociodemographic Characteristics of the Clinic Attendants

The mean age of the clinic attendants in this study was 60±12 which is similar to findings from studies in the subregion (Adediran et al., 2007; Ababio et al. 2017; Falayi et al., 2018), with females found to form a significant majority (69.3%). This finding however is in dissonance with global prevalence studies where the prevalence by sex was found to be similar across gender (Sun et al., 2022) or with a male preponderance (IDF, 2021). It however

affirms observations from other studies where more females were found to attend clinic and report for review more regularly compared to their male counterparts. It has been found that females are more interested in health and seek knowledge about their symptoms than men. Also, females have more schedule flexibility, hence have the greater convenience and accessibility of healthcare services over men (Ladwig et al., 2000).

Majority of the patients (95.2%) who had their medical records reviewed were enrolled on the National Health Insurance Scheme (NHIS). The National Health Insurance Authority recently reported having enrolled almost 16 million clients representing about 54% of the population as per the 2021 census (NHIA 2022). The NHIS cover is designed to cover diabetes care with no cost-sharing requirements and may explain the high subscription rates by attendants at the DM Clinic (NHIS *Benefits Package*, 2023).

Patients enrolled on insurances are less likely to have issues with affordability, which improves compliance on antidiabetic mediations (Goldberg et al., 2016), as against their non-insured/ or Out-Of-Pocket paying counterparts (Aziz et al., 2016; Allaham et al., 2022). The informal sector employed majority of the patients (78.3%) which is in consonance with other studies done on diabetes in Ghana and the African region (Agbozo et al., 2022). Similar to studies done in India (Hannan et al., 2021) and Bhutan (Zam et al., 2015), oral hypoglycaemias were the most commonly used antidiabetic agent.

5.4 Process Indicators

The quality of DM care indicators varies considerably in different continents and countries, primarily due to the difference in healthcare setting. It is however still imperative to assess the quality of care of DM patients with carefully selected indicators as it has a significant impact on the clinical outcomes of the patients (Badawi et al., 2015). The frequency of HBA1C measurement is a key process indicator in assessing the quality of DM care. Among

the medical data analysed, about four-fifths (78.3%) of the DM clinic attendants had had their HBA1C measured at least once in the year under review. This is much higher when compared to studies done in Nigeria (Adeleye & Kuti, 2017), Australia (Imai et al., 2021), Canada (Lyon et al., 2009), and the United States (Deichmann et al., 1999). The recommended HBA1C testing frequency according to the American Diabetes Association (ADA) is at least twice a year. In this present study, only 55 out of the 148 patients whose medical records were reviewed had measured their HBA1C more than once. This inadequacy in HBA1C measurement could be attributed to the high cost of the test since it is not captured by the NHIS.

LDL monitoring was not optimum among the study participants. Approximately half of the participants (51.3%) had at least one LDL level measurement within the year under review, which falls short of ADA recommended guidelines. The ADA recommends an annual LDL monitoring in diabetic patients who have not been tested in the past year. The guidelines further recommend a lipid profile at the time of diagnosis, at the initial medical evaluation, and at least every five years thereafter in diabetic patients under the age of 40 but a higher frequency in very young diabetic patients, like those with type 1 (American Diabetes Association Professional Practice Committee, 2021). The LDL monitoring frequency in this study falls below the frequency of LDL testing reported in some developed countries like France, the United States and Italy (Pornet et al., 2011; Cohen et al., 2017). Compared to a similar study in Sub-Saharan Africa by Adeleye & Kuti (2017) however, the frequency of LDL monitoring in this study is higher. The lower LDL testing frequency recorded in Ghana and the subregion, as compared to the advanced countries, could be attributed to the rising cost of healthcare in developing countries (Fazal et al., 2022), since LDL monitoring is not captured by the national health insurer.

Eye examination had been performed by two-thirds of the study population. On the other hand, foot examination had been done by just half of the participants. The frequency of eye examination was better in this study as compared to several other studies, however, across board foot examination remains a critical but underutilized test (Sarfo-Kantanka et al., 2018; Will et al., 1994; Hartnett et al., 2005; Muñoz et al., 2008; Bailey et al., 1985). A study in the UK (*Diabetes UK, 2012*), however reported a foot examination frequency of 87%. The poor rate of foot examination could be explained by the limited time available for each client at clinic, lack of proper foot examination training (Gallman et al., 2017) and the low number of podiatrists in the country (Bossman et al., 2021). The gender of the clients was noted to be associated with foot examination in this study (p=0.007). Sarfo-Kantanka et al. (2018) observed that foot disorders were more common among Ghanaian males and they are about 3 times more likely to get a lower limb amputation (Sarfo-Kantanka et al., 2019). It is established that increased knowledge and awareness of diabetic foot ulcers can significantly reduce its incidence and improve its clinical outcomes (Fard et al., 2007). The eye examination rate in this study was higher when compared to other studies in Ghana (Ovenseri-Ogbomo et al., 2013; Lartey & Aikins, 2018) and beyond (Muñoz et al., 2008; Paudyal et al., 2008; Saadine et al., 2008; Mwangi et al., 2017; Benoit et al., 2019; Lundeen et al., 2019), yet it fell short with eye examination rates reported in Australia (Tapp et al., 2004), Switzerland (Konstantinidis et al., 2017) and Iran (Javadi et al., 2009). Diabetic retinopathy remains a leading cause of blindness locally and globally, hence it is advised that the test is done annually as recommended by the National Institute of Clinical Excellence (NICE) guidelines, in order to achieve a test rate of 100% (same as foot examination).

Lifestyle modification was done by 80% of the study population. The various forms of lifestyle modification that had been done by the participants include dietary management, weight management, physical exercise, avoiding tobacco smoking and cutting down on alcohol intake. It has been established that lifestyle modification has a positive favourable outcome in the management of diabetes mellitus. Lifestyle modification have been found to reduce symptoms of diabetes (Shrestha & Ghimire, 2012), help patients achieve metabolic control (Franz, 1997), reduce rate of prediabetes and progression to DM (Tuso, 2014) and significantly reduces the risk of developing cardiovascular complications from diabetes (Patel & Keyes, 2023). Smoking status documentation was done for half of the participants (50.8%) which is lower when compared to studies done in Kuwait (Badawi et al., 2015), Finland (Hirvonen et al., 2021) and Malaysia (Blebil et al., 2013). This is highly inadequate since smoking status has a direct bearing on the prognosis of diabetes mellitus. Smoking worsens insulin resistance (Campagna et al., 2019) and increases the rate of DM hospitalization and mortality (Maddatu et al., 2017). This study identified an association between duration of DM and smoking status documentation (p=0.022). According to Blebil et al. (2013), smokers had a shorter duration of diabetes mellitus.

Roughly 18.5%, representing 35 out of the 189 clients whose medical data were reviewed had tested for microalbuminuria. This is significantly low when compared to studies by Hasan et al. (2015) and (Konen et al., 1990; Shin et al., 2021) in Bangladesh and the US respectively, and is highly inconsistent with the ADA recommended guideline of annual microalbuminuria testing. A similar study done in the subregion by Adeleye & Kuti (2017) also recorded a below par frequency of microalbuminuria screening. These poor rates of microalbuminuria screening in the subregion could be attributed to the significant cost associated with the test. Majority of the clients reviewed in this study are employed by the informal sector and rely mostly on the NHIS to cover their hospital charges hence there is huge challenge when it

comes to making out-of-pocket payments. A common and significant long-term complication of diabetes mellitus is diabetic nephropathy, which can lead to chronic kidney disease (CKD). With a prevalence of 13.3% in Ghana (Tannor et al., 2019), CKD is on the rise hence, risk factors and determinants such as diabetes should be closely monitored. Microalbuminuria is an early marker for renal involvement in diabetes (Mogensen et al., 1985), hence it is strongly recommended that patients screen for microalbuminuria annually. Aside being an early marker for diabetic nephropathy, microalbuminuria has also been found to be associated with endothelial dysfunction and cardiovascular disease (de Zeeuw et al., 2006). All participants had a documented BP level. This is because of the no cost that is incurred as BP is recorded routinely when clients turn up for review at the Out-patient Department (OPD).

5.5 Outcome Indicators

The outcome indicators clearly reflect the client's health status and their risk of long-term complications from diabetes mellitus. The mean documented HBA1C in this study was 8.5%, which is similar to another Ghanaian study by Djonor et al. (2021) and a study in Sweden by Nordwall et al. (2014). It was however higher than the figure Ababio et al. (2017) recorded among Ghanaian and Nigerian subjects in their study and separate studies in Nigeria (Adeleye & Kuti, 2017), Japan (Ohde et al., 2018) and the United states (Brown et al., 2004). It has been established that HBA1C levels is a strong predictor of developing long-term diabetic complications (Akselrod et al., 2021). Individuals with an HBA1C level between 8-9% like the participants in this current study have been found to be at the greatest risk of developing myocardial infarction (Azhar et al., 2022). Increasing HBA1C level is also associated with the development of chronic kidney disease (Kang et al., 2015) and cardiovascular complications (Singer et al., 1992). This current study identified an association between HBA1C levels and age ($p<0.01$), duration of DM (<0.001) and the modality of treatment ($p<0.001$). Aging has been associated with increasing HBA1C levels (Dubowitz et al., 2014)

and HBA1C levels have been found to be higher in patients with long-standing diabetes (Raj & Rajan, 2013).

The mean LDL of the participants with a documented LDL level was 2.8 mmol/l. This value is high compared to findings from the United States (Parris et al., 2005) and across 14 different countries in the Treating to New Targets (TNT) study by Shepherd et al. (2006). In the setting of diabetes, the recommended LDL according to the ADA is <2.6 mmol/l. In high-risk groups, the recommended LDL level set by the ADA is <1.8 mmol/l. Roughly 20% (n=38) of the clients whose data were reviewed in this study had the recommended level of LDL <2.6 mmol/l. The poor level of LDL control could be attributed to the low frequency in LDL monitoring as discussed earlier, leading to both clients and caregivers being unable to identify challenges with control and the subsequent introduction of relevant therapies aimed at optimal control. LDL level monitoring (p=0.008) and LDL level (p=0.041) were associated with the employment sector of the clients reviewed in this study. A Ghanaian study by Agongo et al. (2018) earlier established a similar association between gender and LDL. Also, the modality of treatment of DM was associated with LDL level (p<0.001). Kondo et al. (2002) reported that patients on insulin regimen generally have better LDL cholesterol levels. The suboptimal LDL level, in addition to the high HBA1C of the study population (8.5%), put the clients in this study at risk of developing long-term cardiovascular complications from DM such as coronary heart disease (CHD) and stroke (Schofield et al., 2016).

The mean BP of the participants was 142 ± 21.387 for the systolic and 81 ± 11.700 for the diastolic. The mean BP of the study population is high compared to studies across Sub-Saharan Africa and America (Adeleye & Kuti, 2017; Chen et al., 2011). With majority of the clients (58.2%) having a blood pressure reading >140/90 mmHg, they do not meet the recommended BP measurement set by the ADA. Already, hypertension is prevalent in Ghana-27.3% (Tannor et al., 2022), and diabetes is a major risk factor for developing elevated blood pressure levels.

The current BP level (>140/90 mmHg) of the clients involved in this study predisposes them to developing severe long-term cardiovascular complications. Age ($p<0.01$), gender ($p=0.07$), employment sector ($p=0.020$) and duration of DM ($p=0.008$) were all associated with BP control. As reported by several literature, blood pressure levels increases with age (Singh et al., 2023), especially isolated elevated systolic pressure as observed in this study. Males usually have higher BP recordings when compared to females of the same age (Everett & Zajacova, 2015) and Ofori & Obosi (2019) identified that hypertension was more prevalent among formal sector workers. Longer duration of DM has been identified as a prognostic factor for developing hypertension (Alsaadon et al., 2022), hence the need to measure BP regularly in patients with diabetes.

5.6 Strength of the study

This study offers a unique and valuable contribution by addressing a specific aspect of DM care quality that has not been extensively explored in the Ghanaian context. This focused approach allows for a more in-depth examination of the factors influencing DM care quality and provides insights that could inform targeted interventions to improve patient outcomes.

5.7 Limitations of the study

Firstly, due time constraints, a checklist administered to a key informant was used to assess the structures available as compared the principal investigator moving across all sections assessed to ascertain actual situation on the ground. Although availability of input indicators was assessed, readiness could not be assessed within the scope of this study.

Secondly, errors in documentation including omissions due to workload may have provided an inadequate representation of process indicators and outcome indicators assessed in the study

CHAPTER 6

CONCLUSION AND RECOMMENDATION

6.1 Conclusion

Diabetes mellitus remains a common public health concern and a major cause of associated complications and mortality among individuals affected. The burden of diabetes mellitus is skewed towards low to middle-income countries where there is inadequate funding and less robust healthcare systems. Guidelines on the optimum control of diabetes mellitus have been put in place by leading health organizations. This present study identified several inadequacies in the quality of care of diabetes mellitus in clinic attendants at the Greater Accra Regional Hospital (GARH). In terms of service availability and readiness, the hospital's service is near optimum, however, there are several shortcomings in patient clinical process indicators monitoring. The results from this study identified inadequacies in HBA1C monitoring, LDL monitoring, foot examination, smoking status documentation and screening for microalbuminuria.

In addition, documented clinical outcomes were significantly below par in relation to recommended guidelines by the ADA and NICE. The study identified several associations between sociodemographic characteristics and the quality of care indicators.

6.2 Recommendations

The study offers several recommendations aimed at enhancing the quality of care in diabetes clinics, not only in the specific clinic under examination but also across the broader subregion. First and foremost, there is a call for a collaborative effort involving various stakeholders, including the government, health ministry, hospital administration, staff, and most

importantly, the patients. This collective effort is seen as crucial in maximizing optimal care delivery within diabetes clinics.

Furthermore, a specific emphasis is placed on addressing the staffing challenges faced by the clinic. Recommendations include the recruitment of additional staff and the encouragement of individuals to pursue further education in the fields of endocrinology and diabetology. This strategic move is anticipated to alleviate the current workload, reduce waiting times, and ultimately contribute to an increase in the number of clinic attendants. The government and health ministry are urged to play an active role in this aspect by facilitating the employment of more specialized staff and supporting educational initiatives in relevant fields.

Additionally, the study recommends an expansion of the National Health Insurance Scheme (NHIS) package to include crucial diabetes clinical process indicators such as HbA1c, LDL, and microalbuminuria screening. The rationale behind this is to reduce out-of-pocket payments, known to be associated with nonadherence, and thus, enhance the frequency of clinical indicator screenings to align with recommended guidelines.

The responsibility also extends to the clinic staff, including endocrinologists, diabetologists, and nurses, who are encouraged to prioritize patient education and counseling. This involves raising awareness among clinic attendants about the importance of regular monitoring of diabetes care indicators. Clear explanations about the meaning and implications of each clinical outcome are deemed essential to motivate patients to adhere to recommended testing and screening schedules.

Patients themselves are not exempt from the recommendations. It is advised that they attend the clinic regularly, report for scheduled screenings and examinations, and ensure compliance

with prescribed antidiabetic medications. The readiness and availability of clients are deemed equally imperative as the availability and readiness of services.

Finally, the study underscores the need for further research in assessing the quality of care indicators across diabetic clinics nationwide. The associations between the sociodemographic characteristics and these indicators should be closely monitored and assessed in order to know areas where interventions have to be strengthened.

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APPENDICES

APPENDIX 1 – PARTICIPANTS INFORMED CONSENT

QUALITY OF DIABETES CARE AT THE GREATER ACCRA REGIONAL HOSPITAL

Date___/___/2020

Introduction

I am Dr. Delali Kwaku Letsa, a student of the School of Public Health, University of Ghana, who is conducting the above stated study as part of my academic work to fulfill the requirement to the award of Master in Public Health Degree. You can contact me via email at dklets@gmail.com or by phone - 0208962722

Background and Purpose of the study

Diabetes prevalence has increased over the past few years with its attendant challenges posed to the health system and care providers. It has become imperative to assess the quality of care being provided to make relevant recommendations aimed at ensuring good quality care for all diabetics. The purpose of this study is to evaluate the quality of diabetes care provided at the Diabetes Clinic at Greater Accra Regional Hospital by employing the quality indicators approved by the National Diabetes Quality Improvement Alliance (NDQIA) of the United States.

The findings will provide the Hospital Leadership, the Ghana Health Service, Ministry of Health and other stakeholders in the health sector with information that will be used to make policies directed at improving the quality of diabetes care.

Nature of research

This will primarily be a medical audit of clients attendant at the Diabetes clinic over a year's duration. A checklist will also be used to elicit information about the structure (equipment, logistics, personnel etc) from participants. The checklist will be administered in English.

Participation

A key informant will be identified to assist with the completion of the checklist which will be administered by the primary investigator afore mentioned. It should take about 10-20 minutes to complete the checklist.

Although permission has been sought from the head of the facility and other relevant authorities, participation in this study is voluntary and the right to withdraw from the study at any point during the data collection process is maintained. There will be no penalty whatsoever to you if you decide not to partake in this study. Should you decide to withdraw from the study, any information obtained from you will be destroyed.

Consent to participate in this study will require a signature or thumbprint on the consent form and a copy given to you.

Potential Risks

This is a minimal risk study. There is no anticipated physical or psychological risks (heightened emotions, stress, and discomfort) to participation. The time it takes to speak to the interviewer however may be inconvenient.

Benefits

There is no direct benefit of this research to the study participants. However, it is anticipated their participation would inform policy decisions and regulations by relevant stakeholders like the World Health Organization, Ministry of Health, Ghana Health Service, leadership of the hospital among others on the quality of diabetes care on a larger scale. Findings would also serve as a baseline study for researchers interested the assessment and improvement of diabetes care.

Costs

No extra costs would be incurred by participants, since interviews would be conducted within hospital premises, in the comfort of the participant at his/her convenience.

Compensation

There will be no compensation for being a participant in this study. The study is purely for academic purposes, is self funded and participant contributions are solely voluntary with minimal vulnerability of participants

Confidentiality

Information you will share with us during the interviews will be confidential and used only for the purpose of the study.

Feedback

The final report from this study will be presented to all stakeholders as aforementioned as beneficiaries.

Funding information

The study is solely funded by the principal investigator.

Sharing of participants Information/Data

Participant information would not be shared with a third party with the exception of my supervisor who would have access to my records.

Data access and storage

The single copy of this checklist will be transcribed into an electronic form. The hard copy will be destroyed and the electronic form will be secured with a password

Provision of Information and Consent for participants

Copy of the information sheet and consent forms to be signed will be given to the participant to sign

Contact

For clarifications and concerns regarding this study, please contact Dr. Delali Letsa at the Department of Health Policy Planning and Management, School of Public of University of Ghana on 0208962722. You can also contact me via email: dkletsa@gmail.com.

For further clarifications on any ethical issues, kindly contact the Ghana Health Service Ethical Review Committee Administrator, Nana Abena Apatu on 05035539896.

CONSENT FORM

Participant's statement

I acknowledge that I have read or have had the purpose and contents of the Participants' Information Sheet read and all questions satisfactorily explained to me in a language I understand (……name of language). I fully understand the contents and any potential implications as well as my right to change my mind (i.e. withdraw from the research) even after I have signed this form.

I voluntarily agree to be part of this research.

Signature of Participant …….

Thumbprint (participant) ……..

Date ……..

Investigator's Statement

I, the undersigned have explained this consent form to the subject in simple language that he / she understands, clarified the purpose of this study, all procedures to be followed as well as risks and benefits involved. All questions raised by the participant have been duly addressed.

Signature of investigator ……

Date ……

APPENDIX 2 – CHECKLIST AND DATA ABSTRACTION TOOL

Service Availability and Input Checklist / Questionnaire

Leadership/Governance	
Ownership/management of facility	Which Govt Institution does the facility belong to? MOH/GHS Who is the head of the clinic?
Health Care Financing	
Financing of facility / Clinic	
Healthcare financing options utilized in the clinic	What health financing options (NHIS, Private Insurance, Self Sponsored) are available?
Health Workforce	
Health human resources (cadres of health workers)	Kindly indicate the number of each of the following cadre of staff present and active in your clinic or facility • Endocrinologists / Diabetologists • Physician Specialists • Resident Physicians • Medical Officers • House Officers • Nurse Educators • Nurses • Dieticians • Podiatrists • Nephrologist • Any other relevant staff, please specify Have staff members providing diabetes care received any training in diabetes care in the period under review?
Medical Products, Technologies	

Basic equipment	Presence and number of each functional • Blood pressure apparatus • Adult scale • Measuring tape (height board/ stadiometer) • Thermometer • Microfilament
Diagnostics/imaging	Are the following imaging modalities readily available in your facility? • Abdominopelvic USG
Laboratory services	Are the following investigations readily available in your facility? Indicate also if functional • Blood glucose - • Urinalysis – • Glycated Haemoglobin - • Lipid Profile (including LDL) -
Pharmacy and Essential medicines	Are the following medications readily available in your facility? • Oral Metformin • Oral Sulfonylureas • Injectable Insulin • Glucose 50% injectable
Information and Research	
Priority disease caseload register	Is there a disease register in the facility?
Evidence-based guidelines	Are there readily available guidelines for diabetes diagnosis and treatment at the clinic? If yes, Kindly specify
Continuing medical education	Are there regular training programs in Diabetes diagnosis and management? When was the last time a training of such nature was carried out?
Service Delivery	

Basic structural components	How many functional consulting Rooms are routinely used at the clinic? How many practitioners per consulting room?
General clinical services	What are the Clinic hours? What are the average number of clients seen per clinic?

DATA ABSTRACTION TOOL

PARTICIPANT CHARACTERISTICS	
Personal Identification Number	
Age	
Sex	
Insurance Status	Non-Insured NHIS Private Insurance Company Cover
Employment Sector	Formal Informal
Duration of Disease (Since Diagnosis - In years)	
Treatment Modality	Insulin Oral Hypoglycemics Both
BIOCHEMICAL PARAMETERS	
Glucose Monitoring	
- Hemoglobin A1c measurements	None – Once More than twice
- Earliest HbA1C	_____
- Most Recent HBA1C	_____ >9% ? <7% ?
- Home Glucose Monitoring	None- At least once – More than once-
- LDL Monitoring	None Once More than twice
- Most recent LDL value	
CLINICAL CARE	
Eye Care	
- Documented Dilated Eye Examinations	

- Referral to Eye Clinic	
-	
Lifestyle Modification	
- Dietician/Nutritionist Consult	
- Exercise Prescription by Doctor /RD/PT	
Foot Care	
- Documented Foot Exam	
- Peripheral Neuropathy Diagnosis	
Smoking Status Documentation	
Test for microalbuminuria or evidence of medical attention for nephropathy (Diagnosis of nephropathy or documentation of microalbuminuria or albuminuria)	

APPENDIX 3 – GHANA HEALTH SERVICE ETHICAL CLEARANCE

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

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

My Ref. GHS/RDD/ERC/Admin/App/23/255
Your Ref. No.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Digital Address: GA-050-3303
Mob: +233-50-3539896
Tel: +233-302-681109
Email: ethics.research@ghs.gov.gh
19th May, 2023

Delali Kwaku Letsa
P.O. Box LG 13
Legon, Accra

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

GHS-ERC Number	**GHS-ERC: 027/04/23**
Study Title	Quality of Diabetes Care at the Greater Accra Regional Hospital
Approval Date	19th May, 2023
Expiry Date	18th May, 2024
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a 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.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

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 Naa- Korkor Allotey
(Ag. Head, Ethics and Research Management Department)

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