DIABETES DISTRESS AND ITS CORRELATION WITH GLYCEMIC CONTROL AMONG TYPE 2 DIABETES PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA.

BY

IMRAN MAHMUD MOHAMED

A THESIS SUBMITTED IN PARTIAL FULFILLMENT FOR THE AWARD OF MASTER OF MEDICINE DEGREE IN INTERNAL MEDICINE, MOI UNIVERSITY.

DECLARATION

Candidate's Declaration

This proposal is entirely my own work, and has not been submitted to any other university for a degree. Without the author's and/or Moi University's permission, no part of this proposal may be republished.

Imran Mahmud Mohamed,

MS/MED/4888/23

Signature: _____ **Date**: _____

Supervisors' Declaration

As university Supervisors, we have approved the submission of this thesis for consideration.

Dr. Jemima Kamano

Consultant Physician and Endocrinologist

Senior Lecturer, Moi University School of Medicine

Department of Medicine

Signature: _____ **Date**: _____

Prof. Benson N. Gakinya

Professor of Psychiatry

Moi University School of Medicine

Department of Mental Health

Signature: _____ **Date**: _____

DEDICATION

In the name of Allah, the Most Gracious, the Most Merciful without Whose guidance, mercy and wisdom this journey would not have been possible. To my beloved family: my parents and my grandmother, whose prayers, love and sacrifices have been the bedrock of my life; my dear wife, whose unwavering support and patience sustained me through every challenge; my sons (Muhammad and Abdallah), whose presence, innocence and joy give deeper meaning to my efforts; and my siblings, for their constant motivation and belief in me. This work is also dedicated to the countless patients living with diabetes whose resilience and strength continue to inspire the pursuit of compassionate patient-centered care. May this thesis serve as a humble contribution to the advancement of holistic diabetes management and improved health outcomes for all

ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) presents not only a complex metabolic disorder but also imposes a substantial psychological burden in the form of diabetes distress, a condition characterized by negative emotional responses to the ongoing demands of diabetes self-management. This condition continues to emerge as a critical barrier to optimal disease control with growing evidence linking it to poor self-care behaviors, suboptimal glycemic outcomes and increased risk of complications. Despite its clinical relevance, the prevalence of diabetes distress, its associated determinants and impact on glycemic control remain underexplored in many low- and middle-income settings including Kenya.

Objectives: This study aimed to determine the prevalence of diabetes distress among individuals with T2DM, assess their level of glycemic control and evaluate whether diabetes distress independently predicts poor glycemic control.

Methods: A hospital-based cross-sectional study was conducted among 354 adult patients with T2DM at Moi Teaching and Referral Hospital from January 2024 to December 2024. Data on demographic, socioeconomic and clinical characteristics were collected using structured questionnaires. Diabetes distress was assessed using the validated 17-item Diabetes Distress Scale (DDS-17) while glycemic control was evaluated using glycated hemoglobin (HbA1c). Statistical analyses using descriptive statistics, Chi-square and t-tests for bivariate associations, and multivariable logistic regression, was done to assess the correlation between Diabetes distress and glycemic control.

Results: The study population was predominantly female (65.3%), unemployed (67.8%), and uninsured (63.0%), with a mean age of 56.3 years. Over half (52.8%) had coexisting hypertension. The overall prevalence of diabetes distress was 15.8%, with emotional burden (50.3%) and regimen-related distress (33.1%) emerging as the most prominent subdomains. Significant associations were observed between diabetes distress and treatment modality ($p < 0.001$), especially combination therapy, and comorbid hypertension ($p = 0.014$). The mean HbA1c was 9.34%, with 57.4% of participants exhibiting poor or very poor glycemic control (HbA1c $\geq$ 8%). Poor glycemic control was significantly associated with treatment type(insulin) ($p < 0.001$) and occupational status(unemployed) ($p = 0.021$). Importantly, multivariable logistic regression revealed that diabetes distress independently predicted poor glycemic control (AOR = 2.31; 95% CI: 1.16–4.62; $p = 0.017$), indicating that distressed individuals were over twice as likely to have inadequate glycemic control.

Conclusion: Diabetes distress is prevalent among patients with T2DM, with a high proportion also demonstrating poor glycemic control. Diabetes distress was independently associated with poor glycemic outcomes, with affected individuals being more than twice as likely to have inadequate control. Emotional and regimen-related distress emerged as the predominant contributors, highlighting the substantial psychological burden in this population. These findings highlight the necessity of addressing psychological distress as an integral component of diabetes care.

Recommendations: Assessment of diabetes distress should be incorporated into routine diabetes care, particularly for patients with poor glycemic control, given its association with adverse outcomes. Additionally, further research is needed to explore practical and effective strategies for screening and managing diabetes distress within the Kenyan healthcare setting.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS

ADA – American Diabetes Association

AOR – Adjusted Odds Ratio

BMI – Body Mass Index

CDC – Centers for Disease Control and Prevention

CI – Confidence Interval

DDS-17 – 17-item Diabetes Distress Scale

DD – Diabetes Distress

DOPC – Diabetes Outpatient Clinic

DPP-4 – Dipeptidyl Peptidase-4

GLP-1 – Glucagon-Like Peptide-1

HbA1c – Glycated Hemoglobin

HICs – High-Income Countries

HTN – Hypertension

IDF – International Diabetes Federation

IQR – Interquartile Range

IREC – Institutional Research and Ethics Committee

LMICs – Low- and Middle-Income Countries

MTRH – Moi Teaching and Referral Hospital

OR – Odds Ratio

OPD – Outpatient Department

SD – Standard Deviation

SPSS – Statistical Package for the Social Sciences

T2DM – Type 2 Diabetes Mellitus

WHO – World Health Organization

DEFINITION OF TERMS

Diabetes Distress (DD)- Refers to the emotional burden and concerns specifically related to living with and managing diabetes, measured using the DDS-17, with higher scores indicating greater distress.

Diabetes Distress Scale 17(DDS-17) – A standardized tool developed to assess the presence and severity of diabetes distress and its four domains.

Duration of diabetes – this refers to the time period of time in years between time of diagnosis and time of data collection.

HbA1c – this refers to the laboratory measurement of glycated hemoglobin that shall be carried out at the time of data collection.

Treatment modality – this refers to the treatment strategy that is employed for the management of a patient with diabetes at the time of data collection.

Type 2 Diabetes Mellitus – this refers to a patient aged >30 years at time of diagnosis and managed on oral antihyperglycemic or insulin and antihyperglycemics; any patient regardless of age managed on oral antihyperglycemic agent without insulin.

Medication adherence - Taking all anti diabetics agent without failure for the past 7 days

Comorbidity (Hypertension) -The presence of physician-diagnosed hypertension in a patient with type 2 diabetes mellitus at the time of data collection

ACKNOWLEDGEMENTS

I am deeply grateful to my supervisors Dr. Jemima Kamano and Professor Benson Gakinya for their exceptional guidance, mentorship and support throughout the development of this thesis. Their insightful feedback and encouragement have been instrumental in shaping the direction and depth of this work.

I sincerely thank the MTRH Diabetes Outpatient Clinic team and the Laboratory staff for their cooperation and assistance during data collection and laboratory procedures.

To my family, friends and colleagues, thank you for your unwavering support, encouragement and prayers. Your belief in me has been a constant source of strength.

CHAPTER ONE

1.0 Introduction

1.1 Background

Type 2 Diabetes Mellitus (T2DM) is a chronic metabolic disorder marked by hyperglycemia due to insulin resistance and inadequate insulin secretion. Globally, over 451 million people are affected, with projections suggesting this number could reach 693 million by 2045 (Cho et al., 2018). In Kenya, national estimates place the prevalence at around 3–4%, with higher rates in urban areas (Otieno et al., 2021a; Mohamed et al., 2018).

Management of T2DM focuses on lifestyle modification, oral hypoglycemic agents, and insulin therapy to achieve and maintain glycemic targets, thereby reducing the risk of complications such as nephropathy, retinopathy, and cardiovascular disease (Davies et al., 2018). Despite these strategies, many patients fail to achieve optimal glycemic control, as reflected by HbA1c levels, due to various clinical and psychosocial factors (Otieno et al., 2021b).

One key psychosocial factor is diabetes distress (DD) the emotional burden and worry specifically related to living with and managing diabetes. DD has been reported to affect 18–35% of patients and is associated with poor self-care behaviors and worse glycemic outcomes (Alzughbi et al., 2020; Mizokami-Stout et al., 2021). Unlike clinical depression, DD is distinct, situational, and can fluctuate over time. Addressing DD through targeted interventions such as diabetes education, counseling, and peer support has been shown to improve both emotional well-being and glycemic control.

Understanding the association between diabetes distress and glycemic control is essential to designing holistic diabetes care models, improving patient outcomes, and reducing complications, especially in resource-limited settings like Kenya.

1.2 Problem Statement

Diabetes distress (DD) has been shown to negatively affect self-care behaviors, leading to poor glycemic control and higher risk of complications among patients with type 2 diabetes mellitus (T2DM). Early recognition and management of DD can improve both emotional well-being and metabolic outcomes.(Fisher et al 2010)

Globally, routine screening for DD is recommended in diabetes care and has been integrated into practice.(Sturt et al., 2015) However, in Kenya and many other African settings, systematic screening and management of DD are rarely implemented and the psychosocial aspects of diabetes care often receive limited attention in routine practice.

Despite the growing burden of T2DM locally, there is limited evidence on the prevalence of DD, its contribution to poor glycemic control and whether addressing it could improve patient outcomes in Kenya. Local guidelines do not currently emphasize DD assessment and there is a lack of research quantifying its impact among Kenyan patients. This study aims to fill this gap by investigating the association between diabetes distress and glycemic control among patients attending Moi Teaching and Referral Hospital in Eldoret, Kenya.

1.3 Rationale and Justification

Type 2 diabetes mellitus is a lifelong condition that demands continuous self-care, lifestyle adjustments and regular interaction with the healthcare system. While clinical management often focuses on glycemic control and pharmacological treatment, many patients experience emotional and psychological challenges related to living with diabetes.

Studies from various parts of the world have demonstrated that high levels of diabetes distress are associated with poor glycemic control among patients with type 2 diabetes. However, most of this evidence is drawn from high-income countries, with limited data from sub-Saharan Africa. In Kenya, diabetes care is frequently delivered in busy clinical settings where psychosocial aspects of care may be overlooked, despite their potential impact on treatment outcomes.

At Moi Teaching and Referral Hospital (MTRH), many patients attending the diabetes outpatient clinic continue to have suboptimal glycemic control despite regular follow-up and medical treatment. The extent to which diabetes-related emotional distress contributes to this challenge has not been well documented in this setting. The lack of local evidence limits the ability of clinicians to identify patients who may benefit from psychosocial support as part of routine diabetes care. The study aims to provide evidence that can support more holistic and patient-centered approaches to diabetes management in this setting

1.3 Research Questions

What is the prevalence of diabetes distress and its association with glycemic control among Type 2 Diabetes Mellitus patients at Moi Teaching and Referral Hospital, Eldoret, Kenya?

1.4 Research Objective

1.4.1 Broad Objective

To determine the prevalence of diabetes distress and its association with glycemic control among people living with type two diabetes at Moi Teaching and Referral Hospital

1.4.2 Specific Objective

1. To determine the prevalence of diabetes-related distress among type 2 diabetes patients at Moi Teaching and Referral Hospital.
2. To determine the level of glycemic control among patients with type 2 diabetes at Moi Teaching and Referral Hospital.
3. To determine the association of diabetes distress and glycemic control among type 2 diabetes patients at Moi Teaching and Referral Hospital.

1.5 Significance of the Study

T2DM is a significant public health issue in Kenya, and holistic management is essential to achieve optimal glycemic control and prevent disease progression and complications. Previous studies have shown that patients experiencing diabetes distress often have higher HbA1c levels, reflecting poor glycemic control (Fisher et al., 2010a). Importantly, interventions targeting diabetes distress such as structured education, counseling, and psychosocial support have been associated with reductions in distress and corresponding improvements in HbA1c levels (Fisher et al., 2010b; Sturt et al., 2015).

Despite this evidence, at Moi Teaching and Referral Hospital (MTRH) and in the wider region, there is currently no structured effort to routinely screen for or address diabetes distress as part of diabetes care. This gap may contribute to persistent suboptimal glycemic control among patients. Investigating the relationship between diabetes distress and glycemic control locally is therefore critical to inform future integration of psychosocial care into routine diabetes management and to improve patient outcomes.

Recognizing the impact of emotional well-being on treatment adherence and lifestyle changes has the potential to influence clinical practices in Eldoret and elsewhere. Effective interventions based on the study's findings can increase patient engagement, empower people in their self-care journeys, and ultimately contribute to better glycemic control.

Furthermore, the study may have implications for health policies and adds to the evidence base on which health policies can be formulated by shedding light on the interaction between diabetes distress and glycemic control in a specific population. The findings may help to accelerate the incorporation of psychosocial support mechanisms into diabetes management protocols, advocating for a more comprehensive approach to care that takes into account the emotional aspects of T2DM.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview of Diabetes

2.1.1 Definition of Diabetes

Diabetes Mellitus is a metabolic disorder characterized by persistent hyperglycemia (high blood glucose levels) that can be caused by abnormalities in insulin secretion, insulin action, or both. More than 90% of diabetes patients have type 2 diabetes, which is characterized by chronic hyperglycemia, insulin resistance, and, to a lesser extent, insulin secretion impairment.

2.1.2 Epidemiology

Diabetes is an important cause of morbidity and mortality globally. In 2017, there were 425 million individuals living with diabetes globally, and it is anticipated that this number would increase to 629 million by the year 2045. The largest increase in Diabetes is anticipated to occur in countries located south of the Sahara. According to Cho et al. (2017), around 79% of people who have diabetes reside in low- and middle-income countries. Unfortunately, more than two-thirds (69.2%) of Diabetes affected persons residing in Africa are undiagnosed.

According to Forouzanfar et al. (2016), diabetes, together with the other three major non communicable illnesses (cardiovascular disease, cancer, and respiratory disease), is responsible for approximately 80% of all premature NCD fatalities.

The incidence of diabetes is rising at an alarming rate all over the world, and current forecasts point to a significant expansion in the number of people who are afflicted by this condition. According to Hilawe, Yatsuya, Kawaguchi, and Aoyama (2013), there were an estimated 14.7 million adult patients in Africa who were living with diabetes mellitus in the year 2011. Diabetes currently affects around 451 million people

globally, and by 2045, this figure is predicted to rise to 693 million. This rise is expected to be notably notable among individuals aged 65 and older.

The prevalence of diabetes mellitus varies from country to country within Sub-Saharan Africa, However, when all of these factors are considered together, the total incidence rate among adults is quite high, reaching 5.7% (Hilawe et al., 2013). This finding provides more evidence that the region is currently burdened by both communicable diseases and non-communicable diseases, with diabetes serving as a notable illustration of this trend.

Kenya, like many other countries in the region, is not immune to the fast epidemiological transformation that is occurring. A cross-sectional study that was carried out in Kenya with a total of 1,459 (mean age: 38.6 years, range: 17-68 years) participants from rural and urban populations, spanning a wide range of ethnic groups, sheds light on the prevalence of dysglycemia, and documented a prevalence of diabetes at 4.2 percent of participants, and impaired glucose tolerance (IGT) at 12.0% (Otieno et al., 2021a)

According to the national STEP survey for the noncommunicable disease conducted in 2015, the prevalence of diabetes in Kenya was found to be at 2.4% with higher prevalence of pre-diabetes at 3.1% noted (Mohamed et al., 2018).

The findings from Kenya support the general pattern that has been seen throughout Sub-Saharan Africa. These findings also show the urgent need for diabetes care techniques that are both effective and efficient in Kenya

2.1.3 Risk Factors

Type 2 diabetes risk factors can be broadly classified into two main categories: modifiable and non-modifiable factors. These categories encompass a wide range of influences that contribute to an individual's susceptibility to developing diabetes and its associated complications.

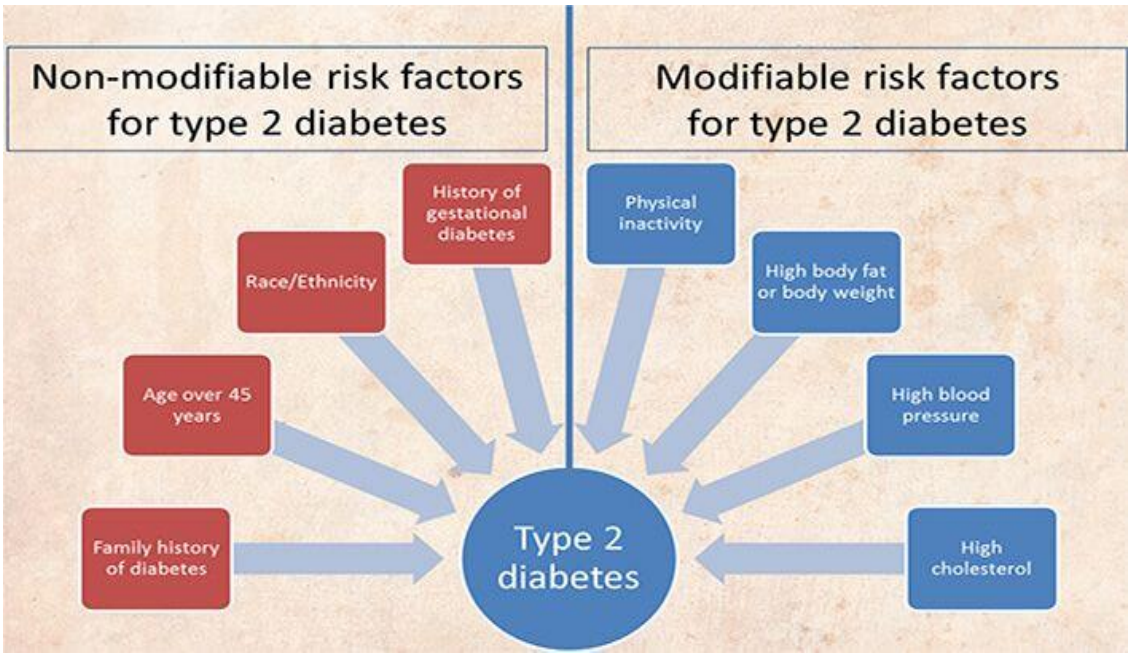


Figure 2.1: Non-modifiable risk factors for type 2 diabetes and modifiable risk factors for type 2 diabetes

Non-Modifiable Risk Factors:

Non-modifiable risk factors are inherent characteristics or circumstances that individuals cannot change. These factors include:

1. Age

The global population of elderly people (those over the age of 60) is growing. The global elderly population of 900 million in 2015 is expected to double to 2 billion by 2050. The risk of metabolic syndrome and chronic diseases such as type 2 diabetes rises with age (Regufe et al., 2020). In an elderly person, aging causes chronic inflammation, which leads to insulin resistance. Furthermore, lipid metabolism disorder caused by aging increases body fat accumulation, resulting in elevated free

fatty acid concentrations in the blood/plasma and, eventually, insulin resistance. As a result, an elderly person is more likely to develop type 2 diabetes.

2. Family history

A family history of diabetes in the first degree of relative (parents, offspring, and siblings) is a strong and independent risk factor for the prevalence of impaired fasting glucose (prediabetes) in children and adolescents(Hu et al., 2019) (OR 11.7, 95 percent 9.5-21.2). In the absence of obesity, this is the case. The findings show that when screening for diabetes in children and adolescents, it is critical to consider the parents' diabetes history. This is due to the fact that only obesity-based screening may result in underestimation. Valdez et al. also discovered that having at least two first-degree relatives with diabetes or one first-degree relative and at least two second-degree relatives with diabetes is associated with a higher risk of type 2 diabetes.

Diabetes in the family reflects both genetic and environmental factors and can lead to a better prediction of type 2 diabetes incidence than genetic and environmental factors alone.

A family history of diabetes increases the likelihood of developing type 2 diabetes. Individuals who have a first-degree relative with diabetes are twice as likely to develop the disease.

3. Ethnicity

Ethnicity is linked to a variety of health complications, including diabetes, due to the diversity of demographic, environmental, and lifestyle conditions. It is a separate risk factor that is exacerbated by social disadvantage and affluent living.

Pacific Islanders (OR 3.1, 95 percent CI 1.4-6.8) have a higher risk of type 2 diabetes than white people (OR 2.3, 95 percent CI 2.1-2.6), followed by Blacks (OR 2.3, 95 percent CI 2.1-2.6), Native Americans (OR 2.2, 95 percent CI 1.6-2.9), Hispanics (OR

2.0, 95 percent CI 1.8-2.3), and Multiracial (OR 1.8, 95 percent CI 1.5-2.9). According to Shai et al., Asians (RR 1.94, 95 percent CI 1.46-2.58), Hispanics (RR 1.70, 95 percent CI 1.28-2.26), and Blacks (RR 1.36, 95 percent CI 1.14-1.63) have a higher risk of type 2 diabetes than whites.

Type 2 diabetes is more common in certain ethnic groups, such as African Americans, Hispanics, and Native Americans. Although the exact causes of this increased risk are unknown, genetic, lifestyle, and environmental factors may all play a role (Spanakis & Golden, 2013).

4. Gestational diabetes

Women who have gestational diabetes during their pregnancy are more likely to develop type 2 diabetes later in life(Kouhkan et al., 2021). During pregnancy, a woman's body undergoes various hormonal and metabolic changes to support the growing fetus some of which can lead to insulin resistance and later on leads to the state of impaired glucose tolerance increasing the risk of developing T2DM.

5. Hypertension

Hypertension is a medical condition characterized by persistently elevated blood pressure in the arteries. Hypertension increases sympathetic nervous system activity, which reduces the body's glucose uptake (Hirooka, 2020). This results in insulin resistance and, eventually, type 2 diabetes. Hypertension increases sympathetic nervous system activity, which impairs skeletal muscle vasodilation. As a result, as type 2 diabetes progresses, muscle glucose uptake decreases.

Modifiable Risk Factors:

Modifiable risk factors refer to those aspects of an individual's lifestyle and behavior that can be altered or controlled through conscious effort and interventions. These factors include:

1. **Obesity**

Obesity is a significant and well-documented risk factor for type 2 diabetes. Obesity is a complex health condition characterized by an excess of body fat. The BMI is used to define it, and the waist-hip ratio is used to assess fat distribution. Inflammation caused by abdominal fat reduces insulin sensitivity by interfering with beta-cell function. Insulin resistance then contributes to the prevalence of type 2 diabetes.

Ohnishi et al. discovered that, when compared to total obesity, central obesity is significantly associated with the risk of type 2 diabetes (RR 2.07, 95% CI 1.03-4.16). This association is stronger in the elderly (60 years) (OR 3.8, 95 percent CI 1.8-7.7). Both men and women have a significant relationship between central obesity and the incidence of type 2 diabetes. However, centrally obese women have a higher risk (OR 2.875, 95% CI 1.987-4.160) than centrally obese men (OR 2.308, 95% CI 1.473-3.615).

2. Physical inactivity

An individual is considered physically inactive if he/she does not get the recommended 30–60 min of exercise three to four times a week. Physical inactivity reduces insulin sensitivity and causes beta-cell loss. This results in impaired glucose tolerance and, ultimately, type 2 diabetes (Booth et al., 2012). However, no research has been conducted to investigate the relationship between physical inactivity as an independent factor and the prevalence of diabetes. One of the reasons that physical

inactivity leads to type 2 diabetes is that it can lead to obesity, which is a significant risk factor for type 2 diabetes.

3. **Glucose intolerance**

It is a condition that impairs the body's ability to maintain normal blood sugar levels. This condition is frequently distinguished by higher-than-normal blood sugar levels after eating (postprandial hyperglycemia) or while fasting (fasting hyperglycemia). It is a stage in the progression from normal glucose metabolism to diabetes. Pre-diabetes conditions that fall between normal glucose metabolism and diabetes include impaired glucose tolerance and fasting glucose(Khan et al., 2019). Adopting a balanced diet, increasing physical activity, losing excess weight, and managing stress are all important for managing glucose intolerance and preventing the progression to diabetes.

4. **Mental health/Depression**

Depression has been linked to a variety of health problems, including diabetes. It stimulates the sympathetic nervous system and the hypothalamic-pituitary-adrenal axis. Increased sympathetic nervous system activity causes an increase in catecholamines and inflammation, eventually leading to insulin resistance(Moulton et al., 2015). Elevated adrenal axis activity, on the other hand, causes an increase in cortisol and, eventually, blood sugar levels. Type 2 diabetes is caused by insulin resistance as well as elevated blood sugar levels.

5. **Smoking**

Smokers are 30-40% more likely than nonsmokers to develop type 2 diabetes. When a person smokes, the level of nicotine in his or her body rises. This causes a decrease in muscle glucose intake, which leads to insulin resistance and type 2 diabetes(Maddatu et al., 2017). Although the reasons for this association are unknown, smoking can

cause inflammation and oxidative stress, which can lead to insulin resistance and metabolic abnormalities.

6. **Sleep disorder**

A person suffering from obstructive sleep apnea (OSA) has two symptoms: 1) a lack of oxygen reaching the tissues due to total or partial collapse of the upper airways while sleeping (hypoxia) and 2) inflammation. Hypoxia causes an increase in sympathetic activity. Increased sympathetic activity and inflammation contribute to insulin resistance and, eventually, type 2 diabetes(Muraki et al., 2018).

7. **Dyslipidemia**

Dyslipidemia is characterized by an abnormally high level of lipids such as triglycerides and cholesterol. It is distinguished by elevated triglyceride levels, increased low-density lipoproteins (LDL), and decreased high-density lipoproteins (HDL). Elevated LDL and decreased HDL levels cause beta-cell dysfunction, which inhibits insulin secretion and, as a result, type 2 diabetes(Hirano, 2018).

Dietary fats that raise total cholesterol and LDL levels are thought to play a role in the development of type 2 diabetes. Substituting polyunsaturated fatty acids and animal fat for vegetable fat can help lower blood cholesterol and, eventually, type 2 diabetes. This is because polyunsaturated fatty acids and vegetable fat are both inversely related to the risk of type 2 diabetes incidence, with RR 0.84 (95 percent CI 0.71-0.98) and RR 0.78 (95 percent CI 0.67-0.91) for the highest quintile of intake, respectively. Tajima et al. found a link between high cholesterol diet intake (>273 mg/day) and type 2 diabetes (RR 1.25, 95 percent CI 1.16-1.36) when compared to low cholesterol intake (185 mg/day).

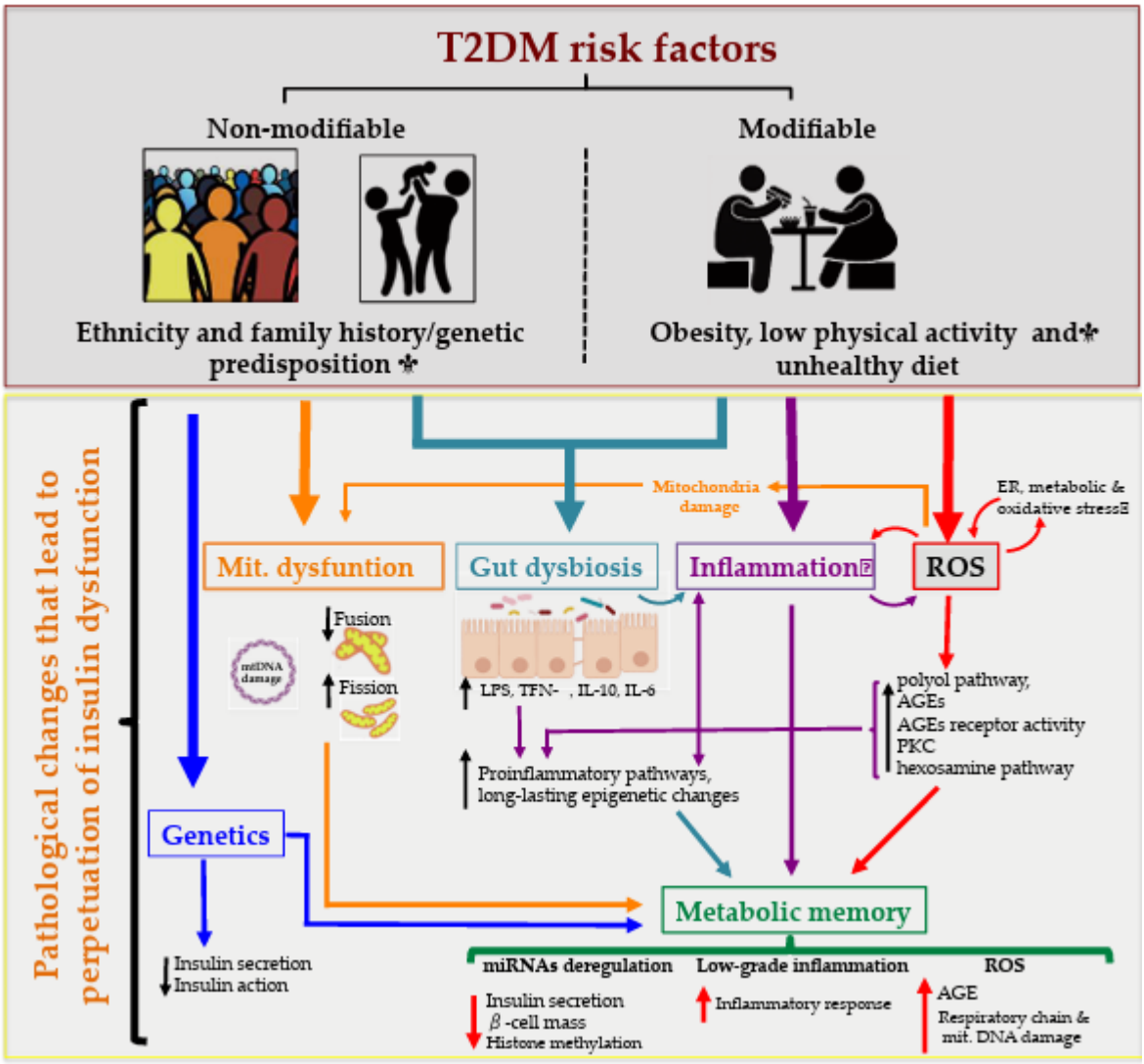
The development of type 2 diabetes is the result of a complex interplay of genetic, lifestyle, and environmental factors. Obesity, physical inactivity, age, family history, ethnicity, gestational diabetes, glucose intolerance, mental health, and smoking are some of the most common risk factors for developing type 2 diabetes(Ismail et al., 2021). Preventive strategies aimed at reducing the incidence of diabetes should focus on addressing these risk factors, encouraging healthy lifestyle habits, and making appropriate medical interventions when necessary.

While these modifiable and non-modifiable risk factors are critical in understanding an individual's susceptibility to type 2 diabetes, it's essential to recognize that social determinants of health also play a significant role in the development of this condition. Social determinants encompass broader societal and environmental factors that influence health outcomes, including diabetes. These factors include socioeconomic status, access to healthcare, education, neighborhood environments, cultural norms, and more. Their impact on an individual's risk of developing diabetes is multifaceted and underscores the importance of addressing social determinants to reduce health disparities and promote overall well-being

2.1.4 Pathogenesis of Type 2 Diabetes

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disease characterized by elevated blood glucose levels. It is responsible for more than 90% of diabetes mellitus cases and can cause damage to multiple organs such as the heart, blood vessels, eyes, kidneys, and nerves. T2DM is associated with impaired insulin secretion by pancreatic islet -cells, tissue insulin resistance (IR), and an insufficient compensatory insulin secretory response. Hyperglycemia develops as the disease progresses due to the failure of insulin production to maintain glucose homeostasis. Diabetes' pathophysiology involves reduced insulin activity and affects a variety of organs and

tissues, including the pancreas, liver, skeletal muscle, adipose tissue, brain, kidneys, and cardiovascular system(DeFronzo et al., 2015).



(García-Sánchez et al., 2020)

Figure 2.2 T2DM Risk Factors

The pancreas (alpha cells and beta cells), liver, skeletal muscle, kidneys, brain, small intestine, and adipose tissue are all involved in the development of type 2 diabetes mellitus (T2DM). Recent data indicates the significance of adipokine dysregulation, inflammation, gut microbiota abnormalities, and immune dysregulation as crucial pathophysiological factors in T2DM. The pathophysiology of T2DM involves a complex interplay between insulin resistance, beta-cell dysfunction, and the gut-brain-liver axis. Insulin resistance occurs when cells are unable to respond to insulin in the

bloodstream effectively. Beta cell exhaustion then occurs as a result of prolonged exposure to high glucose levels. In the early stages of insulin resistance, beta cells respond by secreting more insulin(Petersen & Shulman, 2018). However, prolonged stimulation of beta cells eventually exhausts them, leading to a reduction in insulin secretion. This reduced insulin secretion leads to hyperglycemia, further damaging the beta cells.

Insulin resistance is a hallmark feature of type 2 diabetes (T2DM), which accounts for approximately 90% of all cases of diabetes. Insulin resistance refers to a state in which cells throughout the body become less responsive to the effects of insulin, requiring higher levels of insulin to be produced by the pancreatic β-cells to maintain proper glucose homeostasis (Abdul-Ghani et al., 2019). In T2DM, the mechanisms underlying insulin resistance are complex and multifactorial, and include inflammation, oxidative stress, mitochondrial dysfunction, alterations in the gut microbiota, and epigenetic modifications.

Several pathophysiological mechanisms contribute to the development of insulin resistance. These mechanisms include obesity, inflammation, oxidative stress, and mitochondrial and endoplasmic reticulum stress. Obesity is associated with a state of chronic, low-grade inflammation that involves the production of pro-inflammatory cytokines by adipose tissue. These cytokines promote insulin resistance by activating inflammatory signaling pathways.

Obesity or a greater body fat percentage are common characteristics of patients with type 2 diabetes mellitus (T2DM), with the additional fat primarily distributed in the abdominal area. Adipose tissue promotes insulin resistance by a variety of inflammatory processes, including increased free fatty acid release and adipokine

dysregulation. Global causes including rising obesity rates, sedentary lifestyles, high-calorie meals, and aging population are driving the T2DM epidemic. These variables have contributed to a fourfold increase in the incidence and prevalence of type 2 diabetes(Gómez-Ambrosi et al., 2011).

Insulin resistance and the development of type 2 diabetes are both linked to adipose tissue dysfunction, which is particularly relevant when considering the context of obesity. A further worsening of insulin resistance can be caused by the dysregulated release of adipokines from adipose tissue. These adipokines include adiponectin and resistin, among others. They can disrupt insulin signaling pathways and induce chronic low-grade inflammation(Murdolo & Smith, 2006). These adipokines play key roles in inflammation, insulin signaling, energy balance, and glucose homeostasis. Pro-inflammatory adipokines, such as tumor necrosis factor-alpha (TNF-α), contribute to insulin resistance by activating inflammatory signaling pathways and disrupting insulin signaling. Meanwhile, adiponectin, a potent anti-inflammatory and insulin-sensitizing adipokine, is reduced in obesity and T2D, further contributing to insulin resistance.

When insulin resistance develops in the early stages of T2DM, beta-cell malfunction occurs. Insulin resistance increases the stress on beta cells, causing these cells to release more insulin to compensate. This increased insulin production exhausts and kills beta cells. Beta cells decline in number, size, and function as the disease develops, resulting in a decrease in insulin content and secretion capacity. Furthermore, amyloid accumulation in the pancreas contributes to beta-cell failure(Cerf, 2013).

Another important aspect of T2DM pathophysiology is beta-cell dysfunction, which is caused by a mix of genetic, epigenetic, and environmental factors. With insulin resistance driving up insulin secretion, beta cells experience "glucotoxicity" and increased strain, eventually leading to exhaustion and loss of function. Furthermore, inherited or acquired variables such as amyloid accumulation or inflammation-induced beta-cell death may aggravate their dysfunction, eventually leading to poor glucose homeostasis(Cerf, 2013).

Oxidative stress also plays a critical role in the pathophysiology of T2DM. High glucose levels generate reactive oxygen species (ROS), resulting in cellular damage. Increased ROS levels lead to insulin resistance by inhibiting insulin signaling pathways. Additionally, endoplasmic reticulum stress, mitochondrial dysfunction, and lipotoxicity contribute to the development of insulin resistance(García-Sánchez et al., 2020).

Insulin resistance also occurs at the level of skeletal muscle, where insulin's ability to stimulate glucose uptake is diminished, a condition labeled as "skeletal muscle insulin resistance." Furthermore, the liver plays a crucial role in regulating glucose homeostasis, and insulin resistance in the liver contributes to elevated blood glucose levels in T2DM. In response to lowered insulin signaling, the liver produces glucose via gluconeogenesis thus perpetuating the hyperglycemic state(Merz & Thurmond, 2020).

In recent years, there has been increasing attention given to the role of inflammation in the pathophysiology of diabetes. The presence of a chronic, low-grade state of inflammation characterized by elevated levels of cytokines, chemokines, and acute-phase proteins is observed in metabolic syndrome and obesity. This chronic low-grade

inflammation is partly attributed to dysfunction in adipose tissue and an increased release of cytokines that promote inflammation by immune cells. This inflammatory state plays a crucial role in the development of insulin resistance (IR) and type 2 diabetes T2DM (Calle & Fernandez, 2012). Activation of inflammatory signaling pathways can impair insulin signaling by reducing its downstream signaling capacity and inducing cellular stress. As a result, the inflammation affects the signaling pathways used by insulin, reducing the cells' ability to efficiently take up glucose.

The gut-brain-liver axis is another essential system involved in the pathophysiology of T2DM. Incretin hormones, such as glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP), play a key role in regulating insulin secretion and maintaining glucose homeostasis. When these hormones malfunction, insulin production and glucose homeostasis are disrupted. When a person has type 2 diabetes, their beta cells are less receptive to incretin hormones, resulting in decreased insulin release and poor glucose regulation (Wewer Albrechtsen et al., 2019). The axis also involves the liver's role in glucose homeostasis where the liver's response to insulin is impaired, leading to increased glucose production despite elevated blood glucose levels.

Diabetes pathophysiology has also been linked to the gut microbiota. The gut microbiota is a complex and dynamic community of microbes that encode a diverse set of enzymes and proteins required for digestion, metabolism, and immunological function(Gurung et al., 2020). Certain bacterial species have been linked to metabolic disease progression, and altering the microbiome with antibiotics or nutritional interventions has been proven to improve metabolic status in T2DM patients. The

particular mechanisms underlying the relationship between the gut microbiome and metabolic health, still remain unknown.

The pathophysiology of diabetes involves multiple interconnected processes, including insulin resistance, beta-cell dysfunction, inflammation, gut microbiome alterations, and epigenetic modifications. Effective treatment strategies for diabetes require collaborative efforts from multidisciplinary research teams. Implementing a precision medicine approach that considers patients' individual biological and environmental factors is crucial for interventions. The ultimate goal is to gain a comprehensive understanding of diabetes' pathology, leading to more effective prevention and treatment strategies for this globally significant and debilitating condition.

Significant progress has been made in understanding the pathophysiology of type 2 diabetes mellitus (T2DM). However, there are still clinical challenges in translating this knowledge into effective therapeutic approaches. Current treatment options focus on achieving normoglycemia, improving insulin resistance, and supporting beta-cell function. Promising therapeutic targets include incretin-based therapies, gut microbiota-based therapies, and interventions targeting mitochondrial dysfunction and oxidative stress. The development of effective and personalized treatments for T2DM continues to rely on the collaborative efforts of interdisciplinary teams.

2.1.5 Diagnostic Criteria

The diagnosis of diabetes is based on specific criteria that consider various laboratory measurements and clinical symptoms. According to the American Diabetes Association (“Diagnosis and Classification of Diabetes Mellitus,” 2010), the following criteria are used:

1. Hemoglobin A1C (HbA1C) of 6.5 or higher: The test should be carried out using a method approved by the National Glycohemoglobin Standardization Program (NGSP) and standardized to the Diabetes Control and Complications Trial (DCCT) reference assay.
2. Random plasma glucose concentrations of 11.1 mmol/L (200 mg/dL) or higher: This criterion applies to individuals who present with hyperglycemic symptoms such as polyuria, polydipsia, polyphagia, weight loss, or hyperglycemic crises.
3. An oral glucose tolerance test (OGTT) of 75g that produced a 2-hour postprandial plasma glucose level of 11.1 mmol/L (200 mg/dL) or higher.
4. Fasting plasma glucose concentration of 7 mmol/L (126 mg/dL) or higher: Fasting is defined as cessation of calories consumption for at least 8 hours.

The ADA recommends that the diagnosis be made using two separate test results, either on different days or with the same test.

2.2 Glycemic Control

The monitoring and regulation of blood glucose levels within target levels in T2DM patients is referred to as glycemic control. It is an important part of diabetes management that focuses on the regulation and maintenance of blood glucose levels in diabetics. Its major goal is to keep blood glucose levels within a specified range in order to reduce the risk of disease complications. Short-term and long-term consequences such as cardiovascular disease, kidney disease, retinopathy, and neuropathy can be reduced by enhancing glycemic management(Bin Rakhis et al., 2022).

Glycemic control plays a pivotal role in diabetes management by striving to strike a balance between hyperglycemia and hypoglycemia. This approach aims to minimize

the occurrence of short-term complications and reduce the long-term risks associated with the disease. By achieving optimal glycemic control, individuals with diabetes can enhance their overall health outcomes and reduce the likelihood of complications

There is substantial evidence that patients with type 2 diabetes who manage their blood glucose levels can delay the onset of microvascular complications and lower their severity over time. Taking steps to manage one's glycemia has been demonstrated in a number of trials to lower one's chance of developing complications such as nephropathy, retinopathy, and neuropathy(Giugliano et al., 2018).

Psychosocial factors and clinical factors should be taken into consideration when setting a target range for glycated hemoglobin (HbA1c) levels in individual patients. Factors such as motivation, capacity for self-care, age, coexisting conditions, and the tendency toward hypoglycemia should be considered when determining the appropriate glycemic target for each patient.

Many guidelines have been developed by the American Diabetes Association and the European Association for the Study of Diabetes to provide recommendations for glycemic management in type 2 diabetes patients. These guidelines emphasize the necessity for customized glycemic goals, taking into account psychosocial issues, and advocate for lifestyle adjustments and the use of metformin as first-line therapy. Additionally, they highlight the importance of taking into account psychosocial aspects.

2.2.1 Blood glucose and glycemic control

The term "blood glucose" refers to the concentration of glucose present in the blood. Blood glucose levels are regulated by the interactions between insulin, glucagon, and other hormones, and are influenced by factors such as food intake, physical activity, stress, and metabolic disorders. Abnormal glucose regulation can lead to

hyperglycemia or hypoglycemia, which can result in acute and chronic complications (Lee, 2021).

2.2.2 Pharmacological interventions for glycemic control

Achieving tight glycemic control may necessitate pharmacological interventions, such as insulin, oral hypoglycemic agents, or glucagon-like peptide-1 (GLP-1) receptor agonists. These medications work to lower blood glucose levels by stimulating insulin secretion or increasing insulin sensitivity. Intensive pharmacological interventions can achieve greater glycemic control but are associated with an increased risk of hypoglycemia and other adverse effects, such as weight gain. As such, it is important to tailor glycemic targets and treatment strategies to individual patients based on their clinical characteristics. In some cases, metformin alone may not be sufficient to achieve adequate glycemic control. Patients with chronically high levels of HbA1c or clinically significant hyperglycemia may require additional medications such as insulin therapy or other oral agents like sulfonylureas, DPP-IV inhibitors, or GLP-1 receptor agonists (Taylor et al., 2021).

2.2.3 Lifestyle modifications for glycemic control

In addition to pharmacological interventions, lifestyle modifications including healthy eating and physical activity are important components of glycemic control. Weight loss and regular exercise, in combination with caloric restriction, have been shown to improve glycemic control and reduce the risk of both short- and long-term complications in people with diabetes. Dietary recommendations that emphasize whole grains, fiber-rich vegetables and fruits, and foods low in added sugars, saturated and trans fats, can help improve glycemic control.

Lifestyle approaches play a significant role in improving glycemic control. Weight loss and exercise are important non-pharmacologic strategies that can help regulate

blood glucose levels. The American Diabetes Association recommends a balanced diet rich in fiber, whole grains, and legumes, limited in calories and foods with a high glycemic index, and low in saturated and trans fats. Exercise, when combined with caloric restriction, has an additive effect on glycemic control(O'Donoghue et al., 2021).

2.2.4 Achieving optimal glycemic control

The primary objective of optimal glycemic control is to achieve euglycemia avoiding both hypoglycemia and hyperglycemia with the ultimate goal of preventing complications in individuals with diabetes. Pharmacological and non-pharmacological interventions for glycemic control must be tailored to individual patients considering their clinical characteristics, mental health, and adherence limitations. Additionally, interdisciplinary healthcare teams should prioritize empowering patients to self-manage their condition for effective long-term maintenance of glycemic control(Wang et al., 2023).

Glycemic control is critical for diabetes management, aiming to optimize blood glucose levels and minimize short- and long-term complications. Achieving optimal glycemic control is a continuous process, necessitating individualized treatment strategies and interdisciplinary care(Bin Rakhis et al., 2022). Pharmacological and non-pharmacological interventions can improve glycemic control, considering the patient's clinical characteristics and preferences, adherence, mental health, and financial constraints. Education and regular self-monitoring of blood glucose levels, helps in detecting and preventing hypoglycemic events. HbA1c testing atleast twice a year on the other hand can be used to optimize treatment goals and give an idea about glycemic control over time. Interdisciplinary healthcare teams should prioritize empowering patients to self-manage their condition for effective long-term maintenance of glycemic control.

2.3 Glycemic Control Monitoring

Glycemic control is the result of metabolic mechanisms that regulate blood glucose levels in order to maintain a reasonably tight range of glucose concentration across time. Direct tests of blood glucose, hemoglobin A1c (HbA1c), fructosamine, glycated albumin, and the monosaccharide 1,5-anhydroglucitol are all markers of glycemic control.

Direct blood glucose measurements are the simplest way to monitor glycemic management. Self-monitoring of blood glucose (SMBG) entails patients obtaining blood specimens at home using a finger stick and evaluating glucose concentrations with a glucose meter. Typically, results are immediately available for interpretation(Kirk & Stegner, 2010). The American Diabetes Association recommends SMBG testing at least three times per day for persons with type 1 diabetes and less frequently for patients with type 2 diabetes, depending on the treatment plan of the particular patient.

Fructosamine is another indicator of good glycemic management. The advantage of fructosamine is that it has a shorter half-life than HbA1c. As a result, unlike HbA1c, this measurement may provide information on glycemic variability on a shorter period. However, it has been noted that the relationship between fructosamine and glycemic control is not consistently dependable, and consequences such as renal and hepatic dysfunction can complicate these findings (Malmström et al., 2014).

Glycated albumin is a short-term glycemic control marker that reflects glycemic exposure over a period of 2-3 weeks. It identifies trends in glycemic control that HbA1c may overlook. Because changes in serum albumin levels and some drugs can

affect glycated albumin concentration, significant liver and renal failure can impair its accuracy (Xiong et al., 2021).

1,5-anhydroglucitol (1,5-AG) is a good marker of postprandial blood glucose levels since it reflects glycemic exposure over a week or more. This marker has been reported to provide information in addition to HbA1c, such as the risk of problems in persons with poor glycemic control whose HbA1c may still be within the proper goal range. This measure, however, is regulated by a number of parameters, including the rate of glucose filtration by the kidney and the rate of clearance from the circulation via the urine (Kim et al., 2013).

Continuous glucose monitoring (CGM) is a newer method that has improved fast in the last decade. It delivers extensive personalized information regarding glucose changes throughout the day and night, as well as information on glycemic exposure, trends, and variability over 24 hours. The key advantage of CGM is its capacity to alter therapy based on real-time changes based on readings obtained every few minutes, day or night (Rodbard, 2016).

The most often used glycemic control measure is hemoglobin A1c (HbA1c). It is an average blood glucose concentration during the previous 2-3 months. HbA1c levels have been linked to an increased risk of diabetes complications. HbA1c levels of less than 7% are advised for type 1 diabetes, while HbA1c levels of less than 7% to 8% are recommended for type 2 diabetes, depending on patient features and comorbidities. However, HbA1c has drawbacks, including assay inconsistency, confounding by some hemoglobin variations, and mortality risk at extremely low or extremely high levels.

2.3.1 Use of HbA1c

HbA1c, also known as glycated hemoglobin, is a common biomarker used to assess long-term glycemic management in diabetics. It correlates well with onset of diabetes related complications. Hemoglobin, the iron-containing oxygen-transport protein present in erythrocytes, is made up of a hem moiety and two globin chains, α and β chains (α2β2). They account for roughly 97 percent of adult hemoglobin, with approximately 6 percent glycated within HbA. The major component of glycated hemoglobin is HbA1c (approximately 5%), accompanied by minor components, HbA1a, and HbA1b (both approximately 1%). HbA1c arises from glucose's covalent attachment to the N-terminal valine of the hemoglobin β-chain through a nonenzymatic process known as glycation (De Rosa et al., 1998).

The interaction between blood glucose concentration and erythrocyte lifetime influences HbA1c levels. Given that erythrocytes have a lifespan of about 120 days, HbA1c is a suitable marker for glucose levels throughout the previous 8-12 weeks. Due to the continual turnover of erythrocytes, roughly 50% of a HbA1c value reflects glucose exposure in the previous 30 days, 40% represents exposure from days 31 to 90, and the remaining 10% indicates exposure from days 91-120(Wang & Hng, 2021).

HbA1c was approved by the American Diabetes Association (ADA) in 1988 and has since become the gold standard for measuring glycemic control in diabetes patients. Previously, diabetes was diagnosed using criteria such as fasting glucose, random glucose, or the 75 g oral glucose tolerance test (OGTT). HbA1c was then approved for the diagnosis of diabetes in 2010 after improvements and advances in assays for diabetes at a cutoff of 6.5%, pre-diabetes between 5.7% and 6.4%, and normal 5.7% (Mustafa et al., 2019).

Measurement inaccuracy in HbA1c testing can be influenced by various factors, such as hemoglobinopathies, hemolytic anemia, recent blood transfusions, and certain drug therapies. Additionally, analytical and preanalytical variables, as well as practical aspects like storage and packaging conditions, may contribute to measurement variation and require careful monitoring and regulation. In addition to that, HbA1c testing has limitations in specific populations such as pregnant women, individuals with hemolytic anemia, and patients with renal dysfunction (Chen et al., 2022).

When obtaining and interpreting HbA1c values, several critical factors must be taken into consideration to ensure an accurate assessment of an individual's glycemic control. These factors include measurement accuracy, treatment goals, and comorbidities. Measurement accuracy is paramount in determining the reliability of HbA1c values, therefore standardized and validated methods should be used to measure HbA1c levels, ensuring consistency and precision in the results. Regular calibration and quality control checks are essential to maintain the accuracy of the testing process. Personalized treatment plans should be developed to meet each patient's specific needs, and HbA1c values should be evaluated in light of these individualized goals(Sherwani et al., 2016).

Despite HbA1c's limitations, it is still the most reliable marker in assessing glycemic control(Niwaha et al., 2021) and identifying diabetes control trends in the long-run and the readily available laboratory investigation in our setup.

2.4 Diabetes Distress

2.4.1 Definition

Diabetes distress refers to the emotional and psychological burden that arises from living with diabetes. Patients may experience difficulties adjusting to the diagnosis, managing their blood glucose levels and controlling symptoms. These challenges can have a negative impact on their emotional well-being, leading to stress, anxiety, and depression. Diabetes distress is a complex phenomenon that can affect patients of all ages, genders and races, and can vary in intensity and duration(Islam et al., 2013).

Diabetes distress is defined as the emotional and psychological burden that arises from the demands of diabetes self-management. It is a common and significant issue affecting people living with type 2 diabetes mellitus. The condition may be considered a normal response to the overwhelming nature of dealing with diabetes and its many challenges, such as fluctuating blood sugar levels, medication regimens, dietary changes, and lifestyle modifications.

People with diabetes distress may experience a range of negative emotions, such as anxiety, depression, frustration, anger, guilt, and fear, among others. These emotions may arise from several sources, including concerns about future complications, the perceived inefficacy of treatments, disruptions to one's daily life, interpersonal relationship stress, and the feeling of being overwhelmed by the demands of self-management.

Diabetes distress can significantly affect the quality of life and well-being of those living with diabetes and impede patient self-care, reflecting in poor health outcomes. Studies have suggested that distress arising from diabetes is often higher than the general population's levels, and that there is a considerable variance in levels of

distress experienced between individuals with T2DM and other types of diabetes (Bassi et al., 2021).

It is important to recognize that diabetes distress is different from clinical depression or anxiety. While living with diabetes can provoke anxiety and low mood, diabetes distress refers exclusively to the emotional burden related to managing diabetes, but should not be mistaken for clinical mental health disorders

2.4.2 Epidemiology

The epidemiology of diabetes distress varies across different populations, cultures, and healthcare settings. The prevalence and associated factors can be influenced by various social, psychological, and environmental factors(Abdalla et al., 2020).

1. **Prevalence**: Diabetes distress is prevalent in type 2 diabetes mellitus patients, and varies depending on the study population and assessment instrument used. According to studies, approximately 20% to 50% of persons with T2DM report diabetes related stress (Patra et al., 2021).

2. **Gender**: Some research have revealed that women with diabetes had higher levels of diabetes distress than their males counterparts, whereas other studies have found no significant gender differences in distress level (Batais et al., 2021).

3. **Age:** it is suggested that there may be a U-shaped curve in the relationship between age and diabetes distress. That is, higher levels of distress may be present among the extreme of ages compared to those with middle ages that fall in the middle of the spectrum (Helgeson et al., 2020).

4. **Disease Type**: While diabetes distress is most commonly associated with type 2 diabetes mellitus, it is also documented among individuals with type 1 diabetes or those living with other forms of diabetes (Powers et al., 2017).

5**.Comorbidities**: Other chronic health disorders, such as hypertension, cardiovascular disease, or depression, might increase diabetes discomfort and lead to poor disease self-management and quality of life.

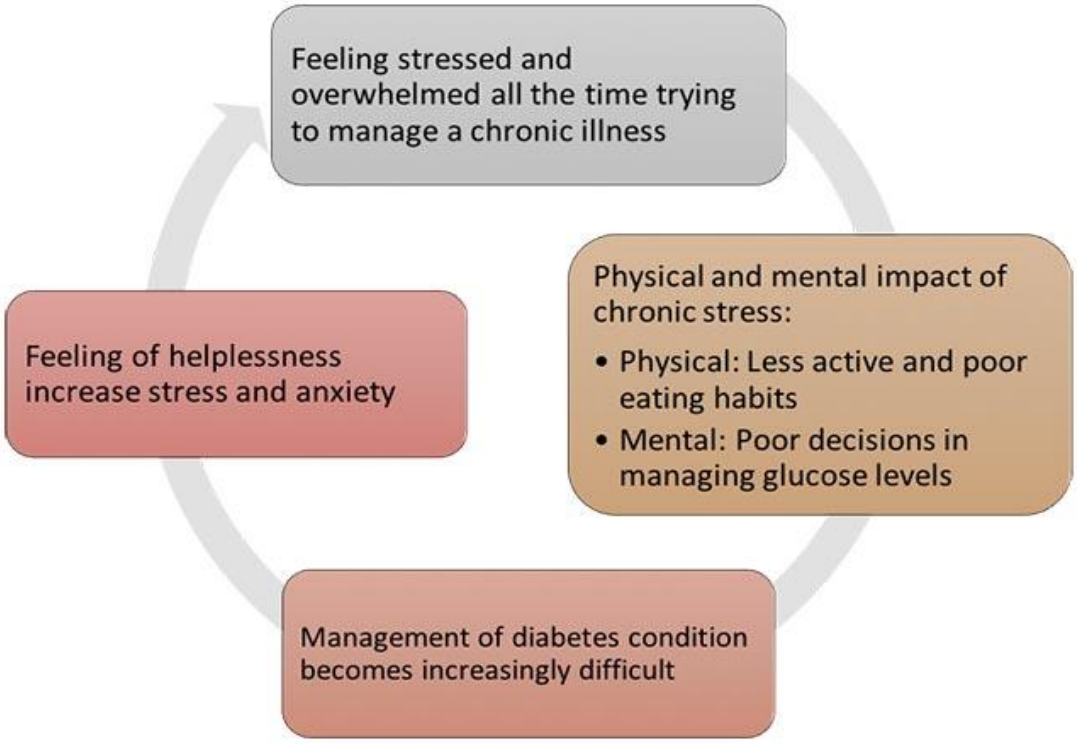
6. **Cultural and ethnic differences**: Cultural and ethnic disparities have been observed in diabetes distress prevalence and impact. Diabetes distress has been more linked to Hispanic, African American, and Native American populations (Walker et al., 2016).

7. **Demographic factors**: Diabetes distress has been linked to a number of demographic characteristics, including low income and low educational attainment. Access to care, social support, and health literacy are all important socioeconomic determinants of health that contribute to the burden of DD (Levy et al., 2022).

2.4.3 Theoretical Framework

A. Stress and coping theories:

Stress and coping theories give a theoretical foundation for studying diabetes distress in people with type 2 diabetes. Individuals with diabetes, according to these ideas, encounter a variety of stresses connected to self-management demands, such as adherence to food restrictions, exercise routines, and prescription regimes(Kalra et al., 2018). According to the Stress and Coping Framework for Type 2 Diabetes Mellitus, distress, which includes psychological stress, might contribute to the development and progression of type 2 diabetes complications by combining with established risk factors such as genetic susceptibility, obesity, and age. This approach stresses the function of coping techniques in distress management and their impact on glycemic control (Minks, 2020).



https://foryoursweetheart.sg/diabetes-and-stress-problems

Figure 2.3: Stress and Coping Theories

B. The role of emotions in diabetes management:

When studying diabetic distress, it is critical to address the function of emotions in diabetes care. Emotional elements such as overwhelm, fear, frustration, and melancholy can all have a substantial impact on an individual's capacity to cope with diabetes and adhere to self-care activities (Rariden, 2019). Understanding the emotional components of diabetes management aids in identifying the emotional issues that individuals confront, as well as its potential impact on glycemic control. Emotional well-being is an important aspect in diabetes self-care, and therapies that address emotions and promote emotional resilience can help with glycemic control (Rariden, 2019).

C. The Biopsychosocial model of diabetes distress:

(MS et al.,

2019a)

Figure 2.4: The Biopsychosocial Model of Diabetes Distress

By taking into account the complex interaction of medical, psychological, and social aspects, the biopsychosocial model provides a complete framework for understanding diabetes distress. This paradigm recognizes that diabetic discomfort is caused not just by medical components of the disease, but also by psychological and social factors such as social support, socioeconomic position, and cultural influences (Minks, 2020). It emphasizes the significance of addressing the multifaceted components of diabetic distress in order to enhance glucose control and general well-being. By taking a biopsychosocial approach, healthcare clinicians can create therapies that address many areas of distress, resulting in better type 2 diabetes management.

D. Association with diabetes-related complications:

Diabetes distress is associated with an increased risk of diabetes-related problems because it imposes a continuous emotional load and stress on people with diabetes. This stress can have a negative impact on their general health and increase the probability of complications. Diabetes distress may have an impact on complications through factors such as poor glucose control, poor adherence to self-care activities, and increased inflammation and oxidative stress.

Diabetes-related chronic discomfort contributes to elevated stress levels, which can affect the body's numerous physiological systems. Prolonged stress can interfere with hormone balance, promote inflammation, decrease immunological function, and raise cardiovascular reactivity, all of which contribute to the development and progression of diabetes problems. Several studies have found a link between diabetic anxiety and complications like retinopathy, nephropathy, neuropathy, cardiovascular disease, and poor wound healing (Mersha et al., 2022). Although the exact mechanisms underlying this association are unknown, chronic stress is thought to cause poor glycemic control, non-adherence to treatment regimens, unhealthy coping behaviors (e.g., smoking or unhealthy eating), and increased activation of stress-related pathways. All of these factors can have a role in the onset and progression of diabetes complications.

Addressing and treating diabetic discomfort is critical to lowering the risk of complications and improving diabetes health outcomes.

E. Impact on quality of life:

Diabetes distress significantly impacts the quality of life in individuals with diabetes. The emotional burden and worries associated with managing this chronic condition affect various aspects of their lives, including physical, psychological, and social well-being.

Physically, diabetes distress results in decreased energy levels, fatigue, and stress-related physical symptoms. It can also worsen diabetes-related symptoms like increased thirst, frequent urination, or neuropathic pain, further impairing daily functioning and overall quality of life.

Psychologically, diabetes distress contributes to higher levels of anxiety, depression, and emotional distress. The constant demands of self-management, concerns about blood sugar control, fear of complications, and feelings of guilt or frustration take a toll on mental well-being and contribute to psychological distress.

Socially, diabetes distress impacts interpersonal relationships, social activities, and overall social functioning. It may lead to social isolation, difficulties in discussing diabetes-related concerns with family and friends, and challenges in participating in social events or activities due to the need for self-care and diabetes management.

Incorporating these theoretical frameworks improves knowledge of diabetes distress in type 2 diabetes patients and its link to glycemic control. These frameworks shed light on the role of stress and coping, the impact of emotions on diabetes treatment, and the larger biopsychosocial environment in which diabetes distress manifests. By addressing these theoretical views, we can be able to come up with comprehensive solutions to manage diabetes distress, enhance effective coping, and maximize glycemic control in people with type 2 diabetes.

Addressing diabetes distress is crucial for improving the quality of life of individuals with diabetes. Providing psychological support, educating on coping strategies, and promoting self-care behaviors can help individuals better manage their distress, leading to enhanced overall well-being and quality of life

2.5 Relationship Between Diabetes Distress and Glycemic Control

2.5.1 Impact of diabetes distress on glycemic control

There was a clear link between diabetic distress and glycemic control (Fayed et al., 2022). Patients who are distressed by their diabetes are more likely to have poor glycemic control. Distress can lead to non-adherence to treatment regimes such as medication, diet, and exercise, resulting in inadequate glycemic control.

A meta-analysis conducted found that higher levels of diabetes distress were associated with poorer glycemic control across various populations in Africa (Fina Lubaki et al., 2022). This study highlighted the negative impact of diabetes distress on glycemic control, emphasizing the need for interventions targeting distress management to improve diabetes outcomes.

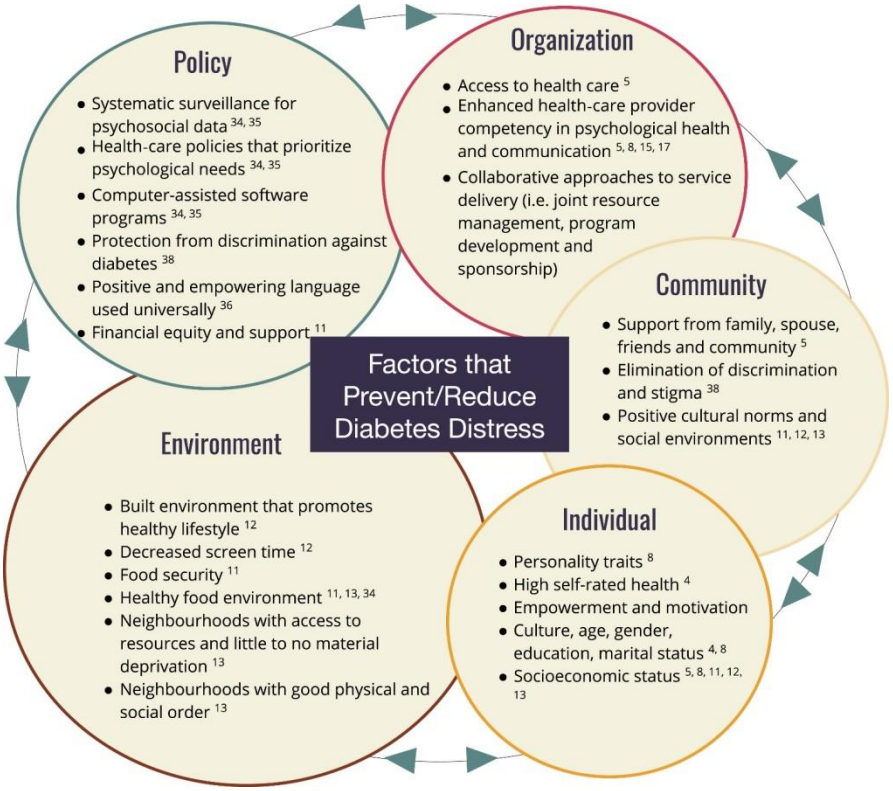
2.5.2 Mediating role of Self-Regulation of Adherence to Treatment (SRAT)

The ability of an individual to regulate and sustain adherence to their diabetes treatment regimen is referred to as self-regulation of adherence to treatment (SRAT). SRAT is important in the interaction between diabetes distress and glycemic control. It functions as a moderator, explaining why diabetes distress has a negative impact on glycemic control.

Patients who are overwhelmed with diabetes stress may struggle with self-regulation, making following their treatment plan challenging. This leads to poor glycemic control and an increase in the risk of complications. Interventions aimed at enhancing SRAT can assist people suffering from diabetes better manage their disease and achieve optimal glycemic control(Fayed et al., 2022b).

2.5.3 Factors influencing the relationship

Several factors influence the relationship between diabetes distress and glycemic control (Ratnesh et al., 2020). These factors include self-efficacy, social support, depression, and healthcare provider communication.



(deMolitor et al., 2020)

Figure 2.5: Factors Influencing the Relationship

Self-efficacy: Self-efficacy is a person's confidence in their capacity to successfully control their diabetes. Better glycemic management has been linked to higher levels of self-efficacy. Individuals suffering from diabetes distress may experience a loss of self-efficacy, which can lead to diminished desire and adherence to treatment regimens.

Social support: Social support plays a crucial role in diabetes management. It can provide emotional support, practical assistance, and encouragement to individuals

with diabetes. Studies have shown that higher levels of social support are associated with better glycemic control [6]. Lack of social support or negative social interactions can contribute to increased diabetes distress and poor glycemic control (Lee et al., 2018).

Depression: Depression is a common comorbidity among individuals with diabetes and is associated with poorer glycemic control. Diabetes distress and depression often coexist and can exacerbate each other. The presence of depression can make it more challenging for individuals to manage their diabetes effectively, leading to suboptimal glycemic control (Hackett & Steptoe, 2017).

Healthcare provider communication: Effective communication between healthcare providers and individuals with diabetes is crucial for optimal glycemic control. Positive and supportive interactions with healthcare providers can help alleviate diabetes distress and improve adherence to treatment plans. On the other hand, poor communication or a lack of understanding from healthcare providers can contribute to increased distress and hinder glycemic control (Khurana et al., 2019).

2.5.4 Interventions for improving glycemic control in diabetes distress

Given the significant impact of diabetes distress on glycemic control, interventions targeting distress management have been developed to improve diabetes outcomes. These interventions aim to address the emotional and psychological aspects of living with diabetes, providing individuals with the necessary tools and support to cope with distress effectively (Tanenbaum et al., 2016).

Cognitive-Behavioral Therapy (CBT): is a widely used intervention for detecting and changing negative attitudes and actions. It has been shown to be effective in lowering diabetes distress and improving glycemic control by assisting patients in

developing coping mechanisms, increasing self-efficacy, and enhancing adherence to treatment regimens (Uchendu & Blake, 2017).

Diabetes Self-Management Education and Support (DSMES): DSMES programs provide individuals with diabetes the knowledge and skills necessary to manage their condition effectively. These programs often include education on nutrition, physical activity, medication management, and problem-solving skills. DSMES has been shown to improve glycemic control and reduce diabetes distress.

Mindfulness-Based Stress Reduction (MBSR): MBSR is a mindfulness-based intervention that focuses on cultivating present-moment awareness and non-judgmental acceptance. It has been found to reduce diabetes distress and improve glycemic control(Whitebird et al., 2018). MBSR helps individuals develop skills to manage stress, enhance self-care behaviors, and improve emotional well-being.

Peer Support Programs: Peer support programs involve connecting individuals with diabetes to others who have similar experiences. These programs provide emotional support, practical advice, and encouragement. Peer support has been shown to reduce diabetes distress and improve glycemic control(Azmiardi et al., 2021). It creates a sense of community and shared understanding, which can alleviate feelings of isolation and burden.

Telemedicine and mobile health interventions: Telemedicine and mobile health interventions utilize technology to provide remote support and monitoring for individuals with diabetes. These interventions can include virtual consultations, remote glucose monitoring, and mobile applications for self-management. They have shown promise in improving glycemic control and reducing diabetes distress. Telemedicine and mobile health interventions offer convenience, accessibility, and personalized support (De Groot et al., 2021).

The relationship between diabetes distress and glycemic control is complex and multifactorial. Diabetes distress can significantly have negative effects on an individual's ability to effectively manage their diabetes, with resultant poor glycemic control and higher incidence of complications. However, interventions targeting distress management have shown promise in improving glycemic control and reducing diabetes distress (Fisher et al., 2010b).

2.6 Diabetes Distress Assessment

Diabetes distress assessment is a crucial component of managing and addressing the psychological and emotional challenges faced by individuals living with diabetes (Aljuaid et al., 2018a). It involves evaluating the impact of diabetes-related stress, worries, and frustrations on a person's well-being and quality of life(Aljuaid et al., 2018b). Various assessment tools have been developed to measure diabetes distress and provide important clinical information for healthcare professionals in tailoring interventions and support strategies (Fisher et al., 2019).

2.6.1 Diabetes distress assessment tools (Dennick Et Al., 2017a)

The following are some of the available tools for diabetes distress evaluation:

Problem Areas in Diabetes (PAID):

PAID is a widely recognized self-report questionnaire that assesses the emotional distress associated with diabetes. It consists of 20 items that capture different aspects of distress, including negative emotions, treatment-related issues, and interpersonal difficulties. Individuals rate the extent to which they experience distress on a Likert scale. Higher scores indicate higher levels of distress, and the tool provides an overall measure of diabetes-related emotional distress(Schmitt et al., 2016).

Diabetes Distress Scale (DDS):

The DDS is another well-established measure for assessing diabetes-related misery. It consists of 17 items and assesses four types of diabetes distress: emotional burden, physician-related distress, regimen-related anguish, and diabetes-related interpersonal disconnect. The DDS provides an overall score as well as domain-specific scores, allowing healthcare providers to gain insight into specific areas of discomfort(Fisher et al., 2012b).

Diabetes Well-being Assessment (DAWN):

DAWN is a comprehensive assessment tool that evaluates various aspects of living with diabetes, including emotional well-being, social support, and healthcare interactions. It comprises multiple scales, such as the Diabetes Health Profile, Diabetes Social Support Scale, and Diabetes Health Perception Scale. DAWN provides a broader assessment of the individual's overall well-being, incorporating both distress and positive aspects of living with diabetes(Skovlund & Peyrot, 2005).

Diabetes-Specific Quality of Life Scale (DSQOLS):

The DSQOLS is a tool that measures the impact of diabetes on an individual's quality of life. It assesses several domains, including satisfaction with diabetes treatment, impact on daily life, diabetes-related worries, and social support. The DSQOLS provides domain scores and an overall quality of life score. It captures the multidimensional aspects of living with diabetes and provides insights into the perceived impact on various life domains(Trikkalinou et al., 2017).

2.6.2 Diabetes distress scale use

The Diabetes Distress Scale (DDS) is a frequently used tool for assessing diabetes-related distress in diabetic patients. Polonsky et al developed the DDS in 2005 as a quick questionnaire for assessing the psychosocial stressors of living with diabetes. The DDS has been validated in different languages and used in numerous studies to

investigate the link between diabetes-related distress and other psychological, behavioral, and clinical outcomes (Fisher et al., 2012).

The DDS is made up of seventeen measures that assess four types of diabetes-related suffering: emotional burden, regimen-related distress, physician-related distress, and interpersonal distress. Each item is evaluated on a 6-point scale ranging from 1 (no issue) to 6 (very difficult) (a very serious problem). The DDS has a total score ranging from 17 to 102, with higher values suggesting greater diabetes-related distress.

The DDS has been shown to have good reliability and validity in various studies. For instance, in a study by Fisher et al at the United States in California, the DDS was found to have good internal consistency (Cronbach's alpha = 0.93) and was strongly correlated with depressive symptoms, anxiety symptoms, and general stress (r = 0.65, 0.50, and 0.69, respectively) (Polonsky et al., 2005).

The DDS has also been found to be a useful tool in clinical practice. In a study by Fisher et al., the DDS was used to identify patients with diabetes who were experiencing significant levels of distress but had not been diagnosed or treated for depression. This led to early intervention and treatment, which improved the patients' quality of life, reduced their diabetes-related distress, and improved their diabetes self-management behaviors (Polonsky et al., 2005).

The DDS has been used in some studies to investigate the association between diabetes-related distress and other outcomes, in addition to its therapeutic value. Diabetes-related distress was found to be negatively correlated with health-related quality of life among individuals with type 2 diabetes. In a study conducted by Chew et al. in Malaysian population it was discovered that diabetes-related distress was

associated with poorer glycemic control, a higher risk of diabetic complications, and higher healthcare expenses (Chin et al., 2017).

Despite its many strengths, the DDS has also been criticized for its narrow focus on psychological distress and its limited coverage of other aspects of diabetes-related stress(Dennick et al., 2017b). For example, the DDS fails to capture the social and environmental stressors that can significantly impact the management of diabetes and the well-being of patients. The Diabetes Distress Scale continues to be a widely used instrument for assessing diabetes-related distress among patients with diabetes. It has good reliability and validity and has been shown to be useful in clinical practice and research. It has been validated for use in Africa in an Egyptian study(MS et al., 2019b).

2.7 Research Gaps in Africa

Despite the growing burden of diabetes in Africa, there is a significant research gap regarding diabetes distress and its association with glycemic control. Previous research has shown the negative impact diabetes distress has on glycemic control. However, most of the research are conducted in high income and developed countries and there is limited data from Africa.

Some Key research gaps in this field include the following:

Prevalence and Severity: It's important to figure out how common and severe diabetes distress is across the various African populations. For the purpose of creating focused therapies and support systems, it is essential to comprehend how much suffering people with diabetes experience and how it varies across various contexts in Africa.

Cultural and contextual factors: The various cultural ideas, traditions, and healthcare systems that define African societies are different to the ones in the west where guidelines and tools for assessment are developed. Research should examine the

relationship between diabetic distress and glycemic management and how cultural and contextual factors affect it. Social norms, access to healthcare services, and traditional healing methods are just a few of the variables that can have a big impact on how people perceive discomfort and how that affects their glycemic control.

Investigating the psychological factors that contribute to diabetic distress in African people is crucial. Diabetes distress and its impact on glycemic control can be influenced by a variety of factors, including social support, family dynamics, socioeconomic status, educational attainment, and health literacy. Knowing these factors will enable the development of solutions that are specifically tailored to the problems Africans with diabetes experience.

Further research and studies aimed at comprehending the connection between diabetes distress and glycemic management in African communities are needed so as to close these gaps.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Location

The research was carried out at MTRH's diabetes outpatient clinics.

3.2 Study Design

A cross-sectional descriptive study to examine the association between diabetic distress and glycemic control in adults with type 2 diabetes.

3.3 Population

Type 2 DM patients attending DOPC

3.4 Eligibility criteria

3.4.1 Inclusion criteria

1. Patients with a confirmed diagnosis of Type 2 Diabetes Mellitus.
2. Patients aged **≥30 years at the time of diagnosis**, to increase the likelihood of true Type 2 diabetes and minimize misclassification with Type 1 diabetes.
3. Patients on treatment with oral hypoglycemic agents and/or insulin.
4. Patients who had been in follow-up at the DOPC for at least **six months**, to ensure adequate exposure to diabetes self-management.
5. Understanding and providing informed consent in our study. Prospective participants were required to demonstrate a clear understanding of the study's purpose, procedures, potential risks and benefits. Providing informed consent is a fundamental requirement for eligibility, ensuring that participants are both willing and adequately informed about their involvement in the research.

3.4.2 Exclusion criteria

1. Patients with Type 1 Diabetes Mellitus, due to differences in pathophysiology, disease progression, and psychosocial burden compared to Type 2 diabetes.
2. Patients with a known history of psychiatric disorders or currently receiving antidepressants or psychotherapy, as these conditions may independently influence emotional distress and confound the assessment of diabetes distress.
3. Patients with current or recent substance abuse (e.g., alcohol, cannabis, opioids, stimulants), defined as harmful or hazardous use that may impair participation or affect psychological assessment.
4. Pregnant women with diabetes, as pregnancy is associated with physiological and psychological changes that may independently contribute to emotional distress and confound diabetes-related distress measurements.

3.5 Sample Size and Sampling Procedure

3.5.1 Sample Size

OBJECTIVE 1:

To Determine the prevalence of diabetes distress among patients with type 2 diabetes at Moi Teaching and Referral Hospital.

The sample size was determined by the **Fisher et al. formula for prevalence studies** (Fisher et al., 1998).

$$n = \frac{Z^2 P (1-P)}{e^2}$$

Whereby:

n= sample size

Z= confidence level at 95% (standard value of 1.96)

P= estimated proportion of diabetes distress 30% - According to a study by (Batais et al., 2021) the prevalence was estimated to be around 29.4% had high distress,

consistent with a recent systematic review and meta-analysis, where females were a higher proportion (Perrin et al., 2017). With other studies in Taif (25%) and Jazan (22.3%) cities (Aljuaid et al., 2018; Alzughbi et al., 2020).

In addition to the global prevalence, we took into account a study conducted in Western Kenya by Jemima et al, which reported a prevalence of depressive symptoms at approximately 22%. (Shirey et al., 2015) Given the interplay between diabetes distress and depressive symptoms, this local study provided valuable insights into the potential prevalence of diabetes distress in our specific region

e= margin of error at 0.05

Substituting for n above: = (1.96*1.96) (0.30) (1-0.30)

$$(0.05)^2$$

= (3.8416*0.3*0.7) / 0.0025

Sample size n = 323

OBJECTIVE 2:

To assess the level of glycemic control in type 2 diabetes patients at MTRH.

$$n = Z^2 P (1-P)$$

$$e^2$$

Whereby:

n= sample size

Z= confidence level at 95% (standard value of 1.96)

P= estimated proportion of glycemic control 36% - The prevalence rate of 36% for Objective 2 was sourced from the 7th Kenyan arm of the International Diabetes Management Practices Study (IDMPs).

e= margin of error at 0.05

Substituting for n above: = (1.96*1.96) (0.36) (1-0.36)

$(0.05)^2$

= (3.8416*0.36*0.64) / 0.0025

Sample size n = 354

OBJECTIVE 3:

To assess the correlation between Diabetes distress and Glycemic control among patients with type 2 diabetes at Moi Teaching and Referral Hospital:

Sample size obtained in objective 2 is powered to assess the correlation between diabetes distress and glycemic control among this population

n = [(Za/2 + Zb)^2 * (1 + rho)^2]/[(1 - rho)^2]

Where:

n = required sample size

Za/2 = the Z value for the desired level of significance (alpha). For alpha = 0.05, Za/2 = 1.96

Zb = the Z value for the desired level of power. For power = 0.80, Zb = 0.84

rho = the correlation coefficient.

Assuming a moderate expected correlation coefficient of 0.50, and values of Za/2 = 1.96 and Zb = 0.84, the sample size calculation would be:

n = [(1.96 + 0.84)^2 * (1 + 0.50)^2]/[(1 - 0.50)^2] = 64.28

Therefore, a sample size of approximately 64 participants would be required to achieve a power of 0.80 at a significance level of 0.05, with a moderate correlation coefficient of 0.50 between diabetes distress and glycemic control

The overall sample size for this study will therefore be 354 as estimated from the second objective and this size is powered for both the 1st and 3rd objectives.

3.5.2 Sampling procedure

This study utilized simple random sampling to recruit participants from the diabetes outpatient clinic (DOPC) at Moi Teaching and Referral Hospital (MTRH). The clinic operates three days per week and attends to approximately 50 patients per day, yielding about 150 patients weekly. Over the 12-week study period, an estimated 1800 patients were seen at the clinic.

On each clinic day, all patients were screened using the inclusion and exclusion criteria to identify eligible participants. Each eligible patient was then assigned a unique identification number sequentially (e.g., 1, 2, 3, …, N).

A random computer-based software number generator was then used to generate random numbers corresponding to these assigned identification numbers. The generated numbers were used to select participants from the list of eligible patients.

For example, if there were 40 eligible patients on a given day, numbers between 1 and 40 were entered into the random number generator, and the selected numbers corresponded to the patients recruited into the study. This process ensured that each eligible participant had an equal and independent chance of being selected, thereby minimizing selection bias.

3.6 Data Collection

3.6.1 Data collection tools:

Data was collected via**:**

1. Sociodemographic questionnaires with age, gender, education level, marital status, medication type, duration of diabetes and comorbidities.
2. Diabetes distress scale was used to screen for Diabetes distress. The DDS has extensive international validation and it has also been used in various countries in Africa, including Egypt, Nigeria and South Africa and has

consistently demonstrated high internal consistency and reliability in assessing diabetes-related distress.

3. Glycemic control was assessed using HbA1c

3.6.2 Data collection procedure

1. **Sampling Timing:** The sampling process was conducted during clinic hours when patients visit for their regular check-ups and consultations.
2. **Consent Procedures:** Eligible participants were identified within the clinic setting and informed consent procedures were rigorously followed. Potential participants were informed about the study's purpose, procedures and risks. Their written informed consent was obtained before any data collection or sampling was initiated.
3. **Replacement of Non-Respondents:** In cases where selected participants declined to provide informed consent or were unable to participate, they were excluded from the study without coercion. Replacement was done by selecting another participant from the remaining pool of eligible patients using the same simple random sampling method.

Procedure for obtaining HbA1c samples and minimizing harm:

1. **Minimizing Harm:** To minimize any potential harm, sample collection was performed by trained healthcare professionals who are well-versed in venipuncture techniques. Strict aseptic procedures were maintained to prevent infection. All equipment used for blood sampling were sterile and disposed off properly.
2. **Testing Process and Responsible Lab:** HbA1c testing was conducted in the hospital's clinical laboratory, which is equipped with state-of-the-art facilities for diagnostic testing. The testing process adhered to standard

operating procedures and quality control measures to ensure the accuracy of the results

3.7 Data Processing and Analysis

3.7.1 Analysis for objective 1

Data cleaning:

The collected data was cleaned to remove any missing or invalid responses.

Cutoff score:

A cutoff score for diabetes distress was determined based on previous research(Fisher et al., 2012a). An average cutoff score of 2 or more on the DDS scale indicated significant diabetes distress**.**

Descriptive statistics:

To describe the prevalence of diabetes distress in the study population, descriptive statistics were used (the mean, median, and standard deviation)

Prevalence calculation:

The prevalence of diabetes distress was calculated as the proportion of participants with a Diabetes Distress Scale (DDS) mean score of ≥ 2.0 relative to the total number of participants included in the study.

Confidence interval calculation:

The standard formula was used to create a confidence interval range for the prevalence estimate:

- Standard deviation = sqrt(p(1-p)/n).

- Error margin = z*SE

- Confidence interval = prevalence +/- margin of error

- Where p represents the predicted prevalence, n represents the sample size, z represents the z-score corresponding to the desired degree of confidence (e.g., 95 percent), and SE represents the standard error.

3.7.2 Analysis for objective 2

HbA1c levels of all the enrolled patients were measured.

Categorization of glycemic control:

Glycemic control was categorized according to the American Diabetes Association's established guidelines (ADA).

Optimal Control: HBA1C <7.0%

Good control: HBA1C 7.0-8.0 %

Poor control: HBA1C 8.0-10%

Very Poor: HBA1C >10%

Descriptive statistics

The mean, median, and standard deviation for glycemic control was calculated.

Frequency distribution tables were created to show the distribution of the HbA1c test results.

The confidence interval for the mean HbA1c level of diabetes patients with diabetes distress was also calculated.

3.7.3 Data analysis for objective 3

Descriptive statistics

In order to summarize the distribution of glycemic control and diabetic distress in the study population, descriptive statistics were utilized.

Inferential statistics

T-test was conducted to evaluate the statistical significance of the difference between the mean HbA1c level of diabetes patients with distress and those without distress.

Correlation analysis

Examining the association between glycemic control and diabetic distress using correlation analysis was done. Pearson's correlation coefficient was calculated to establish whether the relationship between the categorical variables of glycemic control and diabetes distress is linear or nonlinear.

Regression analysis:

After controlling for other variables such as age, gender, duration of diabetes, and comorbidities, regression analysis was conducted to assess whether diabetic distress is a significant predictor of poor glycemic control.

3.8 Ethical Consideration

In adherence to ethical standards, approval from the Institutional, Research and Ethics Committee (IREC) granted. Approval number: FAN0004651. (IREC 678/2023)

Permission was also sought from the administration of The Moi Teaching and Referral Hospital. Informed consent from each participant prior to their participation was sought.

A NACOSTI permit was acquired **License no: NACOSTI/P/25/416268**

The privacy and confidentiality of all participants' data was maintained and meticulously protected throughout the study research.

CHAPTER FOUR

4.0 RESULTS

4.1 Social and Clinical Characteristics

Table 1: Social and Clinical Characteristics

Characteristic	Category	n	%
Sex	Female	231	65.3%
	Male	123	34.7%
Age (years)	<40	57	16.1%
	40–49	66	18.6%
	50–59	95	26.8%
	60–69	80	22.6%
	≥70	56	15.8%
	Mean (SD)	56.3 (15.1)	
Marital Status	Married	241	68.1%
	Widowed	51	14.4%
	Single	44	12.4%
	Separated/Divorced	18	5.1%
Occupational Status	Unemployed	240	67.8%
	Formal employment	50	14.1%
	Informal/other	49	13.8%
	Self-employed	15	4.2%
Health Insurance	Insured	131	37.0%
	Uninsured	223	63.0%
Education	No formal education	24	6.8%
	Primary education	161	45.5%
	Secondary education	121	34.2%

	Tertiary education	48	13.6%
Hypertension	Yes	187	52.8%
	No	167	47.2%
Diabetes Treatment	Insulin monotherapy	127	35.9%
	Oral hypoglycemic agents only	127	35.9%
	Combination therapy (insulin + oral agents)	100	28.2%
BMI Category	Underweight	13	3.7%
	Normal weight	75	21.2%
	Overweight	151	42.7%
	Obese	115	32.5%
Duration of Diabetes	<1 year	42	11.9%
	1–5 years	108	30.5%
	6–10 years	75	21.2%
	>10 years	129	36.4%

Table 4.1 presents the demographic, socioeconomic, and clinical characteristics of the 354 study participants. The majority were female (65.3%), and the mean age was 56.3 years (SD = 15.1), with most participants aged between 50–59 years (26.8%) and 60–69 years (22.6%). Most were married (68.1%) and unemployed (67.8%), while less than half had completed secondary (34.2%) or tertiary (13.6%) education. Only 37.0% reported having health insurance. Clinically, 52.8% had hypertension, and the most common diabetes treatments were insulin monotherapy (35.9%) and oral hypoglycemic agents alone (35.9%). Overweight (42.7%) and obesity (32.5%) were highly prevalent, and more than one-third of participants (36.4%) had lived with diabetes for over 10 years.

4.2 OBJECTIVE 1: Diabetes Distress Scores

Diabetes distress was assessed using four key domains: emotional burden (ED), physician-related distress (PD), regimen-related distress (RD), and interpersonal distress (ID).

A DDS domain score of **≥2.0** is considered indicative of distress.

The total diabetes distress (DDS) was categorized as follows:

1. No distress: = 298 (84.2%)
2. Distress: = 56 (15.8%)

Table 2: Overall Diabetes Distress
Frequency Distribution of Total Diabetes Distress Score

Category	Frequency	Percent
No Distress	298	84.2%
Distress	56	15.8%
Total	**354**	**100.0%**

The majority of the participants (84.2%) reported no overall diabetes distress, while 15.8% experienced distress.

The mean total diabetes distress score among participants was **1.53(CI 1.48-1.58)**

(SD = 0.52), with scores ranging from **1.0 to 4.0**.

Diabetes Distress actual scores

DDS Score	Frequency (n)	Percent (%)
0.9	1	0.3
1.0	40	11.3
1.1	40	11.3
1.2	43	12.1
1.3	28	7.9
1.4	41	11.6
1.5	49	13.8
1.6	25	7.1
1.7	8	2.3
1.8	12	3.4
1.9	11	3.1
2.0	**4**	**1.1**
2.1	**10**	**2.8**
2.2	**5**	**1.4**
2.3	**6**	**1.7**
2.4	**1**	**0.3**
2.5	**10**	**2.8**
2.6	**6**	**1.7**
2.7	**1**	**0.3**
2.8	**1**	**0.3**
2.9	**3**	**0.8**
3.1	**1**	**0.3**
3.2	**3**	**0.8**
3.4	**2**	**0.6**
3.6	**3**	**0.8**
Total	354	100

Table 2A: Emotional Burden
Frequency Distribution of Emotional Burden

Category	Frequency	Percent
No Distress	176	49.7%
Distress	178	50.3%
Total	**354**	**100.0%**

Approximately half (50.3%) of the participants reported experiencing emotional distress related to diabetes, while 49.7% did not.

The mean score for emotional burden was **2.09** (SD = 0.91), with scores ranging from **1.0 to 5.0**.

Table 2B: Physician Distress
Frequency Distribution of Physician Distress

Category	Frequency	Percent
No Distress	329	92.9%
Distress	25	7.1%
Total	**354**	**100.0%**

A majority of participants (92.9%) did not experience distress related to their physician interactions, while only 7.1% reported physician-related distress.

The mean physician distress score was **1.13** (SD = 0.36), with a range of **1.0 to 4.0**.

Table 2C: Regimen Distress
Frequency Distribution of Regimen Distress

Category	Frequency	Percent
No Distress	237	66.9%
Distress	117	33.1%
Total	**354**	**100.0%**

About one-third (33.1%) of the participants reported distress related to their diabetes regimen, while 66.9% did not. The mean score for regimen-related distress was **1.42** (SD = 0.68), ranging from **1.0 to 4.0**

Table 2D: Interpersonal Distress
Frequency Distribution of Interpersonal Distress

Category	Frequency	Percent
No Distress	317	89.5%
Distress	37	10.5%
Total	**354**	**100.0%**

Most participants (89.5%) did not report distress related to interpersonal relationships, while 10.5% experienced such distress. The mean score for interpersonal distress was **1.26** (SD = 0.62), with a range of **1.0 to 5.0**

The mean domain scores for the total diabetes distress score was **1.53**. The highest mean score was observed in the **emotional burden domain** (M = 2.09, SD = 0.91), followed by **regimen distress** (M = 1.42, SD = 0.68), **interpersonal distress** (M = 1.26, SD = 0.62), and **physician-related distress**, which had the lowest mean score (M = 1.13, SD = 0.36). These results indicate that emotional burden was the most commonly reported type of distress among participants

Distribution of Diabetes Distress and Its Association with Sociodemographic and Clinical Factors Using Chi-Square Test

I. Diabetes Distress by Gender

DIABETES DISTRESS LEVEL	FEMALE	MALE
DISTRESS	41	15
NO DISTRESS	190	108
TOTAL	231	123

Chi-square test: $\chi^2(1) = 1.859$, $p = .173$(not significant)

The association between gender and diabetes distress was not statistically significant.

- Among female participants, 17.7% reported distress.
- Among male participants, 12.2% reported distress.

II. Diabetes Distress by Age Group

DIABETES DISTRESS LEVEL	≤40	41–50	51–60	61–70	>70
DISTRESS	5	10	16	18	7
NO DISTRESS	68	45	57	65	62
TOTAL	73	55	73	83	69

The association between age group and diabetes distress was statistically significant.

- In the 51-60 age group, 21.9% of participants reported distress.
- The 61-70 age group had a similar proportion of distress at 21.7%.
- The 41-50 age group showed 18.2% distress.
- For participants aged over 70, 10.1% reported distress.
- 6.8% of the youngest age group (≤40) reported distress.

III. Diabetes Distress by Marital Status

DIABETES DISTRESS LEVEL	MARRIED	SEPARATED /DIVORCED	SINGLE	WIDOWED
DISTRESS	37	2	7	10
NO DISTRESS	204	16	37	41
TOTAL	241	18	44	51

Chi-square test: $\chi^2(3) = 0.889$, $p = .828$

The association between marital status and diabetes distress was not statistically significant.

- Among widowed participants, 19.6% reported distress.
- For single participants, 15.9% reported distress.
- Among married participants, 15.4% reported distress.
- The lowest proportion of distress, 11.1%, was found in the separated/divorced group.

IV. Diabetes Distress by Education Level

DIABETES DISTRESS LEVEL	NONE	PRIMARY	SECONDARY	TERTIARY
DISTRESS	1	25	18	12
NO DISTRESS	23	136	103	36
TOTAL	24	161	121	48

Chi-square test: $\chi^2(3) = 5.576$, $p = .134$

The association between education level and diabetes distress was not statistically significant.

- Among participants with tertiary education, 25.0% reported distress.
- For those with a primary education, 15.5% reported distress.
- Among those with a secondary education, 14.9% reported distress.
- 4.2% of the group with no formal education reported distress.

V. Diabetes Distress by Occupational Status

DIABETES DISTRESS LEVEL	EMPLOYED	SELF-EMPLOYED	UNEMPLOYED	OTHER
DISTRESS	4	6	39	7
NO DISTRESS	46	9	201	42
TOTAL	50	15	240	49

The association between occupational status and diabetes distress was statistically significant.

- 40.0% among self-employed participants reported distress.
- Among unemployed participants, 16.3% reported distress.
- For the 'other' occupational category, 14.3% reported distress.
- 8.0% of employed participants reported distress

VI. Diabetes Distress by Insurance Status

DIABETES DISTRESS LEVEL	INSURED	NOT INSURED
DISTRESS	19	37
NO DISTRESS	112	186
TOTAL	131	223

The association between insurance status and diabetes distress was not statistically significant.

- Distress was reported by 16.6% of participants without insurance.
- Among those with insurance, 14.5% reported distress.

VII. Diabetes Distress by Duration of Diabetes

DIABETES DISTRESS LEVEL	<1 YEAR	1–5 YEARS	6–10 YEARS	>10 YEARS
DISTRESS	5	18	6	27
NO DISTRESS	37	90	69	102
TOTAL	42	108	75	129

Chi-Square p-value: 0.089 (not significant)

The association between the duration of diabetes and diabetes distress was not statistically significant.

- 20.9% of participants who had diabetes for more than 10 years reported distress
- For those with diabetes for 1-5 years, 16.7% reported distress.
- Among those with diabetes for less than 1 year, 11.9% reported distress.
- The lowest proportion of distress (8.0%) was found in the group with diabetes for 6-10 years.

VIII. Diabetes Distress by Treatment Type

DIABETES DISTRESS LEVEL	INSULIN ALONE	INSULIN + ORAL	ORAL MEDICATION ONLY
DISTRESS	6	32	18
NO DISTRESS	121	68	109
TOTAL	127	100	127

Chi-Square p-value: <0.001 (significant)

The association between treatment type and diabetes distress was statistically significant.

- 32.0% of participants on a combination of insulin and oral medication reported distress
- For those on oral medication only, 14.2% reported distress.
- 4.7% participants on insulin alone reported distress.

IX. Diabetes Distress by BMI Category

DIABETES DISTRESS LEVEL	UNDERWEIGHT	NORMAL	OVERWEIGHT	OBESE
DISTRESS	1	9	23	23
NO DISTRESS	12	66	128	92
TOTAL	13	75	151	115

Chi-Square p-value: 0.389 (not significant)

The association between BMI and diabetes distress was not statistically significant.

- Among obese participants, 20.0% reported distress.
- For overweight participants, 15.2% reported distress.
- Among participants with a normal BMI, 12.0% reported distress.
- 7.7% of participants found in the underweight group reported distress.

X. Diabetes Distress by Hypertension Status

DIABETES DISTRESS LEVEL	NO HYPERTENSION	HYPERTENSION
DISTRESS	18	38
NO DISTRESS	149	149
TOTAL	167	187

Chi-Square p-value: 0.014 (significant)

The association between hypertension and diabetes distress was statistically significant.

- Among participants with hypertension, 20.3% reported distress.
- For those without hypertension, 10.8% reported distress.

4.3 OBJECTIVE 2: Level of Glycemic Control

The glycemic control status of the study participants was assessed using HbA1c levels and categorized as follows:

1. **Optimal Control**: HbA1c < 7%
2. **Good Control**: HbA1c 7–8%
3. **Poor Control**: HbA1c 8.1–10%
4. **Very Poor Control**: HbA1c > 10%

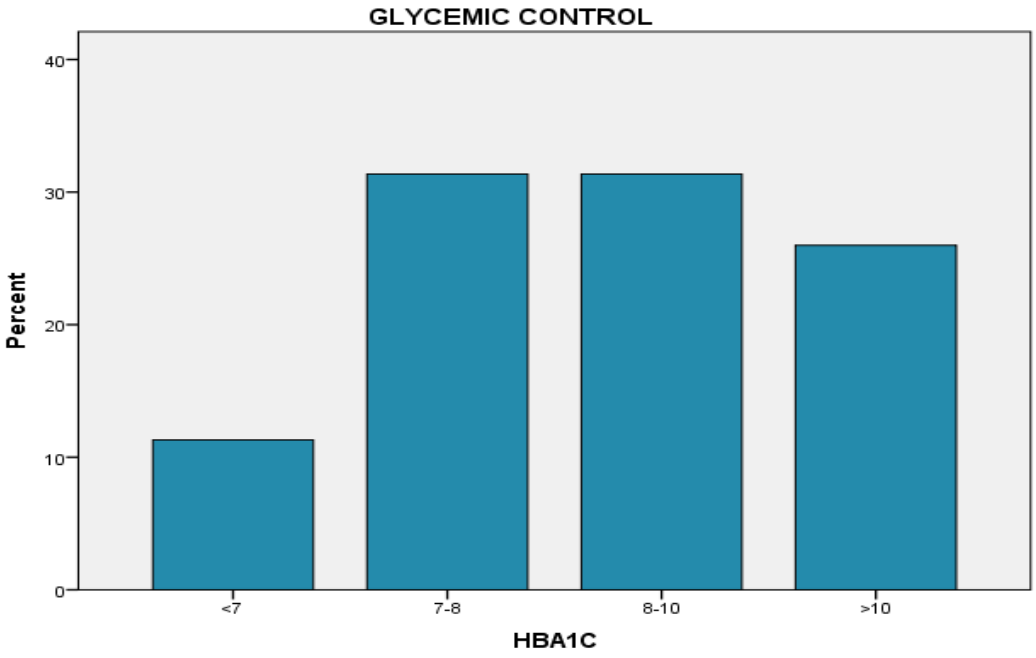


Table 3: Distribution of HBA1C Categories

HbA1c Category	Frequency	Percentage (%)
Optimal Control (HbA1c <7%)	40	11.3%
Good Control (HbA1c 7–8%)	111	31.4%
Poor Control (HbA1c 8.1–10%)	111	31.4%
Very Poor Control (HbA1c >10%)	92	26.0%
Total	**354**	**100.0%**

Out of the 354 participants, 11.3% had optimal glycemic control with HbA1c levels below 7%. A larger proportion, 31.4% had HbA1c levels within the 7–8% range, classified as good control. Similarly, 31.4% fell within the poor control category, with HbA1c levels between 8.1% and 10%. The remaining 26.0% had very poor control, with HbA1c levels exceeding 10%.

Measure	HbA1c Value / Category
Mean	**9.34%(CI 9.07- 9.63)**
Median (50th percentile)	**Poor Control (8.1–10%)**
Standard Deviation (SD)	**2.57**

The mean HbA1c level among the study participants was 9.34% (SD = 2.57), with values ranging from a minimum of 5.0% to a maximum of 26.0%. This implies that the average glycemic control in the study was poor.

Standard Deviation: 2.57

There is moderate variability in HbA1c levels across the population.

Interquartile Ranges

25% of patients have HbA1c ≤8% (Optimal or Good Control).

50% of patients have HbA1c ≥8.1%, half of the population has Poor or Very Poor control.

25% of patients have HbA1c >10%, having very poor control

Table 3A: Distribution of Glycemic Control (HbA1c Categories) Across Sociodemographic and Clinical Characteristics Using Chi-Square Test

The characteristics analyzed include sex, marital status, age group, education level, BMI, duration of diabetes, insurance status, occupational status, treatment type and hypertension status.

I. HbA1c vs. Sex

HbA1c Category	Female	Male
Optimal (<7)	32	8
Good (7-8)	69	42
Poor (8.1-10)	70	41
Very Poor (>10)	60	32
Total	231	123

Chi-Square p-value: 0.578 (not significant)

The association between sex and glycemic control was not statistically significant.

- Among female participants, 30.3% had poor control and 29.9% had good control.
- Among male participants, 34.1% had good control and 33.3% had poor control.

II. HbA1c vs. Age Group

HbA1c Category	30-40	41-50	51-60	61-70	>70
Optimal (<7)	7	6	7	8	12
Good (7-8)	16	20	30	28	17
Poor (8.1-10)	17	17	18	31	28
Very Poor (>10)	33	12	19	16	12
Total	73	55	73	83	69

The association between age group and glycemic control was statistically significant.

- In the 30–40 age group, 45.2% had very poor control.
- Among those aged 41–50, 36.4% had good control.
- In the 51–60 age group, 41.1% had good control.
- In the 61–70 group, 37.3% had poor control.
- For participants above 70 years, 40.6% had poor control.

III. HbA1c vs. Marital Status

HBA1C Category	Married	Separated/ Divorced	Single	Widowed
Optimal (<7)	32	0	2	6
Good (7-8)	76	9	12	14
Poor (8.1-10)	69	9	9	24
Very Poor (>10)	64	0	21	7
Total	241	18	44	51

Chi-Square p-value: 0.360 (not significant)

The distribution of HbA1c levels varied by marital status, though the association was not statistically significant.

- Among married participants, 31.5% had good control and 28.6% had poor control.
- For separated/divorced participants, 50.0% had good control and 50.0% had poor control.
- Among single participants, 47.7% had very poor control.
- Among widowed participants, 47.1% had poor control.

IV. HbA1c vs. Occupational Status

HbA1c Category	Employed	Self-Employed	Other	Unemployed
Optimal (<7)	2	2	8	28
Good (7-8)	11	7	18	75
Poor (8.1-10)	16	2	14	79
Very Poor (>10)	21	4	9	58
Total	50	15	49	240

Chi-Square p-value: 0.021 (significant)

The distribution of HbA1c levels showed a statistically significant association with occupational status.

- Among employed participants, 42.0% had very poor control and 4.0% had optimal control.
- For self-employed participants, 46.7% had good control.
- In the “other” category, 36.7% had good control.
- Among unemployed participants, 32.9% had poor control and 31.3% had good control.

V. HbA1c vs. Education Level

HbA1c Category	None	Primary	Secondary	Tertiary
Optimal (<7)	4	24	7	5
Good (7-8)	5	39	52	15
Poor (8.1-10)	5	60	30	16
Very Poor (>10)	10	38	32	12
Total	24	161	121	48

Chi-Square p-value: 0.401 (not significant)

The association between education level and glycemic control was not statistically significant.

- Among participants with no formal education, 41.7% had very poor control.
- For those with a primary education, 37.3% had poor control.
- Among those with a secondary education, 43.0% had good control.
- For participants with tertiary education, 33.3% had poor control.

VI. HbA1c vs. Insurance Status

HbA1c Category	Insured	Not Insured
Optimal (<7)	13	27
Good (7-8)	48	63
Poor (8.1-10)	42	69
Very Poor (>10)	28	64
Total	131	223

Chi-Square p-value: 0.254 (not significant)

The association between insurance status and glycemic control was not statistically significant.

- Among insured participants, 36.6% had good control and 32.1% had poor control.
- For those without insurance, 30.9% had poor control, 28.7% had very poor control, and 28.3% had good control.

VII. HbA1c vs. Duration of Diabetes

HbA1c Category	<1 Year	1-5 Years	5.1-10 Years	>10 Years
Optimal (<7)	6	14	5	15
Good (7-8)	15	39	23	34
Poor (8.1-10)	7	29	24	51
Very Poor (>10)	14	26	23	29
Total	42	108	75	129

Chi-Square p-value: 0.190 (not significant)

There was no significant association between the duration of diabetes and glycemic control.

- For participants with diabetes for less than 1 year, 35.7% had good control.
- Among those with diabetes for 1–5 years, 36.1% had good control.
- In the 5.1–10 years group, 32.0% had poor control, with 30.7% having good control and 30.7% very poor control.
- For participants with diabetes for more than 10 years, 39.5% had poor control.

VIII. HbA1c vs. BMI

HbA1c Category	<18	18-25	25.1-30	>30
Optimal (<7)	2	7	21	10
Good (7-8)	4	17	51	39
Poor (8.1-10)	2	22	45	42
Very Poor (>10)	5	29	34	24
Total	13	75	151	115

Chi-Square p-value: 0.164 (not significant)

There was no significant association between BMI category and glycemic control.

- Among those with BMI <18, 38.5% had very poor control.
- For participants with BMI 18–25, 38.7% had very poor control.
- Among those with BMI 25.1–30, 33.8% had good control.
- For BMI >30, 36.5% had poor control.

IX. HbA1c vs. Treatment

HbA1c Category	Insulin	Insulin + Oral	Oral
Optimal (<7)	14	3	23
Good (7-8)	34	23	54
Poor (8.1-10)	38	44	29
Very Poor (>10)	41	30	21
Total	127	100	127

Chi-Square p-value: < 0.001 (**highly significant**)

There was a strong, significant association between treatment type and glycemic control.

- Among insulin users, 32.3% had very poor control and 29.9% had poor control.
- For those on insulin plus oral medication, 44.0% had poor control.
- Among oral medication users, 42.5% had good control.

X. HbA1c vs. Hypertension

HbA1c Category	HTN	No HTN
Optimal (<7)	24	16
Good (7-8)	62	49
Poor (8.1-10)	63	48
Very Poor (>10)	38	54
Total	187	167

Chi-Square p-value: 0.180 (not significant)

There was no significant association between hypertension and glycemic control.

- Among participants with hypertension, 33.7% had poor control and 33.2% had good control.
- Among those without hypertension, 32.3% had very poor control.

4.4 objective 3: To describe the association of diabetes distress and glycemic control

COMPARISON OF MEANS

Participants were categorized into two groups based on the total DDS score: Distress and No distress. The mean HbA1c level for those without distress group was 9.21 (SD = 2.574), while the distressed group had a mean HbA1c of 10.00 (SD = 2.463).

Table 4A: Mean HbA1c by Diabetes Distress Category

Diabetes Distress Category	N	Mean HbA1c	Standard Deviation
No Distress (DDS < 2)	298	9.21	2.57
Distress (DDS ≥ 2)	56	10.00	2.46
Total	354	9.34	2.57

Table 4B: Independent Samples t-Test Comparing HbA1c by Diabetes Distress Status

Test	t-value	df	p-value	Mean Difference	95% CI (Lower–Upper)
Equal variances assumed	-2.12	352	0.035	-0.788	-1.521 to -0.056
Equal variances not assumed	-2.18	79.29	0.032	-0.788	-1.507 to -0.069

An independent samples t-test was conducted to compare HbA1c levels between these two groups. Levene's test indicated equal variances ($F = 0.001$, $p = 0.981$). The t-test revealed a statistically significant difference in HbA1c levels between the two groups, $t(352) = -2.117$, $p = 0.035$, with the high distress group exhibiting significantly higher HbA1c levels. The mean difference was -0.788 (95% CI: -1.521 to -0.056).

Table 4C(i): Correlation Analysis between diabetes distress and glycemic control

Variable Pair	Pearson (r)	p-value	Significance
HbA1c × Total DDS Score	0.112	**0.035**	*Significant at 0.05*

A Pearson correlation analysis showed a weak but statistically significant positive correlation between DDS scores and HbA1c levels (r = 0.112, p = 0.035), indicating that higher diabetes distress was associated with higher HbA1c.

Domain specific distress	Correlation with HbA1c (r)	p-value	Significance
Emotional Burden (ED)	0.071	0.185	Not significant
Physician Distress (PD)	0.105	0.049	*Significant at 0.05
Regimen Distress (RD)	0.130	0.014	*Significant at 0.05
Interpersonal Distress (ID)	0.140	0.008	**Significant at 0.01

Pearson correlation analyses revealed that among the four domains of diabetes-related distress, three were significantly associated with glycemic control. **Physician distress** (r = 0.105, p = 0.049), **regimen distress** (r = 0.130, p = 0.014), and **interpersonal distress** (r = 0.140, p = 0.008) all showed weak but statistically significant positive correlations with HbA1c, suggesting that higher distress in these areas was modestly linked to poorer glycemic control.

In contrast, **emotional burden** was not significantly correlated with HbA1c (r = 0.071, p = 0.185), indicating no meaningful linear relationship in this domain.

However, it is important to note that the study was not specifically powered to detect these correlations within each subdomain and the sample sizes in some distress categories may have been insufficient to fully explore these associations. Therefore, these findings should be interpreted with caution and future studies with larger sample sizes are recommended to validate these results.

Table 4d: Regression Analysis
Binary Logistic Regression of Diabetes Distress and Glycemic Control

Predictor	B	SE	Wald	p-value	Odds Ratio (Exp(B))	Interpretation
Diabetes Distress	0.532	0.309	2.961	0.085	1.702	Not statistically significant

A binary logistic regression analysis was conducted to assess whether diabetes distress was a significant predictor of poor glycemic control (defined as HbA1c ≥ 8%). The overall model was not statistically significant ($\chi^2 = 3.080$, $p = 0.079$), indicating that the presence of diabetes distress did not significantly improve the prediction of glycemic control status.

The regression coefficient for diabetes distress was positive but not statistically significant ($B = 0.532$, $p = 0.085$). The corresponding odds ratio (Exp(B) = 1.702) suggests that participants with distress had 1.7 times higher odds of poor glycemic control compared to those without distress; however, this association did not reach statistical significance.

The model explained approximately **1.2% of the variance** in glycemic control (Nagelkerke $R^2 = 0.012$) and correctly classified **57.3%** of cases.

Table 4E: Multivariable Logistic Regression Predicting Poor Glycemic Control

Predictor	OR (Exp(B))	95% CI	p-value	Interpretation
Diabetes Distress (Yes)	**2.31**	**1.16 – 4.59**	**0.017**	Significant. Distress has higher odds of poor control
Treatment (Insulin)	**3.39**	**1.97 – 5.83**	**<0.001**	Significant. Insulin users more likely to have poor control
Sex (Female)	0.57	0.33 – 1.01	0.054	No significant association
Other confounders (BMI, HTN, Age, Marital, Insurance, Education, Duration)	—	Not significant	>0.05	No independent associations detected

A multivariate logistic regression analysis was conducted to determine whether diabetes-related distress is an independent predictor of glycemic control among patients with type 2 diabetes, after adjusting for potential confounding factors including demographic, social, and clinical variables.

The overall model was statistically significant ($\chi^2 = 61.17$, $df = 24$, $p < 0.001$), indicating that the full set of predictors reliably distinguished between individuals with good versus poor glycemic control. The model explained approximately **21.4%** of the variance (Nagelkerke $R^2 = 0.214$) and correctly classified **70.0%** of cases.

Diabetes distress remained a **significant independent predictor** of poor glycemic control ($p = 0.017$). Participants experiencing distress were **2.3 times more likely** to have poor glycemic control compared to those without distress (OR = 2.31, 95% CI: **1.16-4.59**).

Treatment type was highly significant with patients on insulin having **3.39 times(CI: 1.97 – 5.83)** higher odds of poor control compared to those on oral agents ($p < 0.001$).

Sex showed a borderline association with glycemic control, with females having lower odds of poor control (OR = 0.574; 95% **CI: 0.33–1.01).** However, the confidence interval crossed 1, indicating that this association was not statistically significant.

Other variables, including age group, BMI, marital status, education, insurance status, hypertension and duration of diabetes were not significantly associated with glycemic control after controlling for other factors.

CHAPTER FIVE

5.0 DISCUSSION

5.1 Demographic and Clinical Characteristics of Study Participants

The study population predominantly consisted of females (65.3%), with a mean age of 56.31 years. The majority were married (68.1%) and unemployed (67.8%), and over half (63.0%) lacked health insurance. Hypertension was a common comorbidity, affecting 52.8% of participants. These demographic and clinical profiles are generally consistent with patient populations observed in other studies on type 2 diabetes particularly in low and middle income settings which often reflect prevailing societal structures and healthcare access disparities. The high prevalence of unemployment and lack of health insurance underscores potential socioeconomic vulnerabilities that can impact diabetes management and access to care.

5.2 Diabetes Distress

5.2.1 Overall Diabetes Distress Prevalence

The study found that 15.8% of participants experienced overall diabetes distress, with a mean total distress score of 1.53. This prevalence is lower than some figures reported globally and within Sub-Saharan Africa. A meta-analysis indicated that 36% of adults with type 2 diabetes globally experience diabetes distress while as high as 50% were reported in China(Zhang et al., 2024) A study from Nigeria, a Sub-Saharan African country, reported a distress prevalence of 24.08% (Noman et al., 2021). The relatively lower prevalence in this study might be attributed to various factors including cultural coping mechanisms, differences in assessment tools or the specific characteristics of the study population. It is also possible that some participants misunderstood certain items in the questionnaire, or that the results may have differed had the tool been validated specifically for this population. Nonetheless, the findings

still indicate that a notable proportion of patients struggle with the distress burden of diabetes.

5.2.2 Domain-Specific Diabetes Distress

Emotional burden was the most prevalent domain of distress (50.3%), followed by regimen-related distress (33.1%). Physician-related distress (7.1%) and interpersonal distress (10.5%) were less common. The prominence of emotional burden aligns with the understanding that living with a chronic condition like diabetes often leads to feelings of frustration, fear and being overwhelmed by the constant demands of self-management(Polonsky et al., 2005) . The high regimen-related distress suggests challenges with adherence to complex treatment plans, diet and lifestyle modifications which are central to diabetes care(Polonsky et al., 2005). The lower rates of physician and interpersonal distress could reflect relatively supportive healthcare interactions and social environments within the study context, or simply indicate these areas are less burdensome for the participants. In contrast, a study from Nigeria reported emotional distress at 28.96%, interpersonal at 23.61%, physician at 16.42%, and regimen at 13.21% indicating variations in the most impactful domains across different populations.

5.2.3 Factors Associated with Diabetes Distress

1. **Gender:** While the study found no statistically significant association between gender and diabetes distress, a higher proportion of females reported distress (17.7% vs. 12.2% for males). Some literature suggests that females may experience higher levels of diabetes distress(Zhang et al., 2024)which might be due to various psychosocial and cultural factors related to caregiving roles or healthcare seeking behaviors.

2. **Age:** The study observed a trend of increasing distress with age, peaking in the 51-70 age range. This contrasts with some studies suggesting that older age is associated with *lower* diabetes distress (Polonsky et al., 2005)or that younger age is associated with higher distress(Zhang et al., 2024) .This divergence could indicate specific stressors for older adults in the study population, such as increased burden of complications, financial strain, or social isolation not fully captured by general age categories.
3. **Education Level:** Although not statistically significant, participants with tertiary education reported the highest proportion of distress (25.0%). This could be interpreted as individuals with higher education having greater awareness of their condition and its complexities potentially leading to more distress or it might be due to unique stressors associated with their occupational or social roles. Another possible explanation is that the more educated cohort may have understood the questionnaire items better, thereby reporting their distress more accurately.
4. **Duration of Diabetes:** The study did not find a significant association between diabetes duration and distress, though those with diabetes for more than 10 years had the highest proportion of distress. This aligns with findings that longer duration of diabetes with its associated complications and accumulated management burden can contribute to increased distress
5. **Treatment Type:** A significant association was found between treatment type and diabetes distress, with participants on combination therapy experiencing the highest distress (32.0%). A recent population-based study in Norway also found that insulin based regimen was significantly associated with higher diabetes distress among adults with type 2

diabetes.(Riise et al., 2025) This is a crucial finding, as more intensive and complex treatment regimens (e.g., insulin plus oral agents) inherently place a greater burden on patients, requiring more rigorous self-management, monitoring, and lifestyle adjustments.

6. **Body Mass Index (BMI):** While overweight and obese participants had slightly higher distress scores, the association was not statistically significant. This lack of significance could be due to the multifactorial nature of diabetes distress where psychosocial, cultural and support system factors may play a greater role than BMI alone. It is also possible that in our study population, weight-related stigma or body image concerns are less pronounced, reducing the impact of BMI on distress levels.
7. **Hypertension (HTN):** The study revealed a statistically significant association between hypertension and diabetes distress, with hypertensive participants experiencing higher distress levels (20.3%). This finding is consistent with existing research indicating that comorbidities like hypertension contribute to increased psychological distress in individuals with diabetes(Simelane et al., 2025). The co-occurrence of these conditions often leads to a more complex management regimen and a heightened risk of complications increasing the overall burden on the patient

5.3 Glycemic Control

5.3.1 Overall Glycemic Control

The mean HbA1c level in the study population was 9.34%, with a significant proportion (57.4%) having poor or very poor glycemic control (HbA1c ≥8.1%). This indicates suboptimal glycemic management among the majority of participants. This level of poor control is a concern especially when compared to findings in other Sub-Saharan African contexts where less than one-third of individuals with diabetes are reported to achieve glycemic targets. This highlights the pervasive challenge of achieving optimal glycemic control in resource-constrained settings, influenced by factors such as limited access to healthcare as well as medication adherence issues and lifestyle challenges.

5.3.2 Factors Associated with Glycemic Control

1. **Occupational Status:** The study found a significant association between occupational status and glycemic control. Employed individuals, particularly those self-employed, showed varying levels of control. This aligns with research suggesting that occupational factors, such as long working hours or job-related stress, can impair self-management and lead to poorer glycemic control(LEE et al., 2020).The nuances of occupational demands and flexibility can greatly influence a patient's ability to adhere to their diabetes regimen.
2. **Treatment Type:** A strong and statistically significant association was observed between treatment type and glycemic control. Patients on oral medication alone had the highest proportion of optimal control while those on insulin alone or combination therapy had a higher proportion of very poor glycemic control. This finding is expected as insulin therapy and combination regimens are typically initiated when oral medications alone are insufficient to

achieve glycemic targets indicating a more advanced or severe form of diabetes. This pattern is consistent with clinical practice where more intensive therapies are reserved for patients with more difficult-to-control blood glucose levels.

3. **Sex:** The study found no statistically significant association between sex and glycemic control. This contrasts with some research, for example, a study in Ethiopia that reported women having poorer glycemic control than men(Kautzky-Willer et al., 2015)). Other studies also acknowledge marked gender differences in glucose control. The lack of a significant difference in this study could be due to specific population characteristics or other unmeasured confounding factors.
4. **BMI:** No statistically significant association was found between BMI category and glycemic control. Interestingly, normal-weight individuals had a high proportion (68.0%) of poor or very poor glycemic control. This finding while not significant, warrants further investigation as it may suggest that factors beyond BMI are more influential in glycemic management within this specific population or that normal weight individuals with diabetes may have different underlying disease progression or self-management challenges.
5. **Hypertension:** There was no statistically significant association between hypertension and glycemic control in this study. While hypertension is a common comorbidity that can exacerbate diabetes complications, its direct influence on glycemic control can vary and may be mediated by other factors or managed through concurrent treatment.

5.4 Association Between Diabetes Distress and Glycemic Control

The study's most significant finding is the clear association between diabetes distress and glycemic control. A statistically significant positive correlation was found between total diabetes distress scores and HbA1c levels ($r = 0.112$, $p = 0.035$) which shows that higher distress is associated with poorer glycemic control. Participants experiencing distress had significantly higher mean HbA1c levels (10.00%) compared to those without distress (9.21%) ($p = 0.035$).

This crucial relationship was further supported by the multivariable logistic regression analysis which identified diabetes distress as a significant independent predictor of poor glycemic control (OR = 2.31, $p = 0.017$) after adjusting for various demographic social and clinical factors. Although diabetes distress did not show a significant association with glycemic control in the univariate analysis it emerged as a significant independent predictor in the multivariate model. This suggests the presence of confounding influences such as treatment modality and occupational status that initially obscured the relationship. Adjusting for these covariates in multivariate analysis allowed the true effect of diabetes distress to be revealed and highlighting its critical role in glycemic control. These findings emphasize the need for comprehensive patient assessments that account for both psychological and clinical factors when addressing diabetes management.

This means that individuals experiencing diabetes distress were more than twice as likely to have poor glycemic control. This bidirectional relationship implies that high HbA1c can increase frustration, guilt, and fear particularly in patients who feel they are failing at management despite their efforts. In turn, this distress erodes their motivation and energy for self-care, perpetuating a cycle of poor control.

These findings are strongly corroborated by a substantial body of international literature. A meta-analysis involving data from 61 studies and nearly 20,000 participants concluded that depression and diabetes distress are significantly associated with poorer glycemic control (Wojujutari Ajele & Sunday Idemudia, 2025). Similarly, a study from Northwest Ethiopia highlighted that elevated distress levels are associated with poorer glycemic control, increased risk of complications, and decreased adherence to treatment plans(Sendekie et al., 2025).

Research consistently shows that diabetes distress impacts self-management behaviors leading to challenges in medication adherence, blood glucose monitoring and lifestyle modifications, all of which are critical for achieving optimal glycemic control. The mechanism often involves a vicious cycle where distress makes self-management more difficult, leading to poorer control, which in turn exacerbates distress.(Polonsky et al., 2005).

Among the specific domains of distress, physician distress, regimen distress, and interpersonal distress showed significant positive correlations with HbA1c in this study. This suggests that challenges in these areas directly impact a patient's ability to manage their diabetes effectively. However, it is important to note that the study was not specifically powered to analyze the individual domains, and these findings should therefore be interpreted with caution. In contrast, emotional burden did not show a significant correlation with HbA1c ($p=0.185$) in this analysis.

5.5 Strengths and limitations of the study

5.5.1 Strengths

1. **Objective Glycemic Measurement:** Utilized HbA1c which is a reliable biomarker for precise assessment of glycemic control.
2. **Robust Statistical Analysis**: Applied appropriate statistical methods, including multivariable logistic regression to identify independent predictors.
3. **Broad Variable Inclusion**: Incorporated a wide range of demographic clinical and psychological variables providing a comprehensive dataset for analysis.

5.5.2 Limitations

1. **Cross-Sectional Design**: unable to the establish cause-and-effect relationships or temporal sequences between variables.
2. **Limited Generalizability:** Study findings may not be universally applicable due to the specific cultural and socioeconomic context of the sampled population.
3. **Distress Assessment Tool:** While a validated tool was used for the diabetes distress assessment, it had not been specifically validated for the East African population, but rather for a different demographic in Egypt. This may have introduced a degree of uncertainty regarding the instrument's accuracy and the generalizability of the distress scores.

CHAPTER SIX

6.0 Conclusions and Recommendations

6.1 Conclusion

The study established that a notable proportion of the participants (15.8%) experienced diabetes distress and revealed a high prevalence of suboptimal glycemic control, with over half of the participants (57.4%) having poor or very poor HbA1c levels. This study also demonstrated a significant and independent association between diabetes distress and poor glycemic control among patients with type 2 diabetes.

The analysis further showed that treatment type and hypertension status were significantly associated with distress. Regimen-related distress and emotional burden were identified as the most prominent domains of distress. These findings underscore the critical need for holistic, patient-centered approaches to diabetes care that integrate psychological support alongside medical management to improve glycemic outcomes and overall well-being.

6.2 Recommendations

6.2.1 Clinical Practice

1. **Routine Screening for Diabetes Distress:** Healthcare providers should routinely screen for diabetes distress using validated tools like the DDS, particularly in patients presenting with suboptimal glycemic control or those on complex treatment regimens.
2. **Patient-Integrated Care:** Interventions should address both the physiological and psychological aspects of diabetes management. Mental health support, including counseling and educational programs focused on coping strategies for emotional and regimen-related distress, should be integrated into standard diabetes care.

3. **Centered Education:** Tailored educational programs are needed to help patients manage the burden of complex treatment regimens and to improve their interactions with healthcare providers and support networks.
4. **Targeted Support:** Given the higher distress levels in patients with hypertension and those on combination therapy these groups may benefit from more intensive psychological support and education.

6.2.2 Future Research

1. **Longitudinal Studies:** Future research should employ longitudinal and mixed-method study designs to identify and evaluate effective strategies for reducing diabetes distress and improving glycemic control within the Kenyan context. Such studies would provide deeper insight into the mechanisms linking distress and glycemic outcomes, while also determining context-appropriate interventions that can be integrated into routine diabetes care.
2. **Qualitative Research:** Qualitative studies could provide deeper insights into the specific experiences and contextual factors contributing to diabetes distress in this population.

6.3 Publication and Dissemination

To ensure that the findings of this study contribute meaningfully to both scientific knowledge and clinical practice, a comprehensive publication and dissemination strategy has been developed. The goal is to maximize the visibility and impact of the research, foster evidence-based diabetes care, and promote the integration of psychological assessment in chronic disease management.

The dissemination strategy will include the following key activities:

1. **Scientific Journal Publication**

   The study findings will be submitted to peer-reviewed journals specializing in diabetes care, psychosocial health, or public health so as to facilitate knowledge sharing among academics, clinicians, and policy stakeholders globally.

2. **Conference Presentations**

   The research will be presented at both national and international scientific conferences focused on diabetes, internal medicine, and non-communicable disease (NCD) care.

3. **Local Dissemination through Workshops and Seminars**

   Dissemination will also target healthcare professionals, patients and hospital administrators through tailored workshops and seminars at Moi Teaching and Referral Hospital (MTRH). These forums will focus on translating findings into practice by emphasizing the role of diabetes distress screening and its integration into routine care.

REFERENCES

Abdul-Ghani, M. A., Jayyousi, A., DeFronzo, R. A., Asaad, N., & Al-Suwaidi, J. (2019). Insulin Resistance the Link between T2DM and CVD: Basic Mechanisms and Clinical Implications. *Current Vascular Pharmacology*, *17*(2), 153–163. https://doi.org/10.2174/1570161115666171010115119

Azmiardi, A., Murti, B., Febrinasari, R. P., & Tamtomo, D. G. (2021). The effect of peer support in diabetes self-management education on glycemic control in patients with type 2 diabetes: a systematic review and meta-analysis. *Epidemiology and Health*, *43*, e2021090. https://doi.org/10.4178/epih.e2021090

Bassi, G., Gabrielli, S., Donisi, V., Carbone, S., Forti, S., & Salcuni, S. (2021). Assessment of Psychological Distress in Adults With Type 2 Diabetes Mellitus Through Technologies: Literature Review. *Journal of Medical Internet Research*, *23*(1), e17740. https://doi.org/10.2196/17740

Batais, M. A., Alfraiji, A. F., Alyahya, A. A., Aloofi, O. A., Almashouq, M. K., Alshehri, K. S., Almizel, A. M., Alotaibi, M. T., & Alosaimi, F. D. (2021). Assessing the Prevalence of Diabetes Distress and Determining Its Psychosocial Predictors Among Saudi Adults With Type 2 Diabetes: A Cross-Sectional Study. *Frontiers in Psychology*, *12*. https://doi.org/10.3389/fpsyg.2021.759454

Bin Rakhis, S. A., AlDuwayhis, N. M., Aleid, N., AlBarrak, A. N., & Aloraini, A. A. (2022). Glycemic Control for Type 2 Diabetes Mellitus Patients: A Systematic Review. *Cureus*. https://doi.org/10.7759/cureus.26180

Booth, F. W., Roberts, C. K., & Laye, M. J. (2012). Lack of Exercise Is a Major Cause of Chronic Diseases. In *Comprehensive Physiology* (pp. 1143–1211). Wiley. https://doi.org/10.1002/cphy.c110025

Calle, M. C., & Fernandez, M. L. (2012). Inflammation and type 2 diabetes. *Diabetes & Metabolism*, *38*(3), 183–191. https://doi.org/10.1016/j.diabet.2011.11.006

Cerf, M. E. (2013). Beta Cell Dysfunction and Insulin Resistance. *Frontiers in Endocrinology*, *4*. https://doi.org/10.3389/fendo.2013.00037

Chen, Z., Shao, L., Jiang, M., Ba, X., Ma, B., & Zhou, T. (2022). Interpretation of HbA1c lies at the intersection of analytical methodology, clinical biochemistry and hematology (Review). *Experimental and Therapeutic Medicine*, *24*(6), 707. https://doi.org/10.3892/etm.2022.11643

De Groot, J., Wu, D., Flynn, D., Robertson, D., Grant, G., & Sun, J. (2021). Efficacy of telemedicine on glycaemic control in patients with type 2 diabetes: A meta-analysis. *World Journal of Diabetes*, *12*(2), 170–197. https://doi.org/10.4239/wjd.v12.i2.170

De Rosa, M. C., Sanna, M. T., Messana, I., Castagnola, M., Galtieri, A., Tellone, E., Scatena, R., Botta, B., Botta, M., & Giardina, B. (1998). Glycated human hemoglobin (HbA1c): functional characteristics and molecular modeling studies.

Biophysical Chemistry, *72*(3), 323–335. https://doi.org/10.1016/S0301-4622(98)00117-3

DeFronzo, R. A., Ferrannini, E., Groop, L., Henry, R. R., Herman, W. H., Holst, J. J., Hu, F. B., Kahn, C. R., Raz, I., Shulman, G. I., Simonson, D. C., Testa, M. A., & Weiss, R. (2015). Type 2 diabetes mellitus. *Nature Reviews Disease Primers*, *1*(1), 15019. https://doi.org/10.1038/nrdp.2015.19

deMolitor, L., Dunbar, M., & Vallis, M. (2020). Diabetes Distress in Adults Living With Type 1 and Type 2 Diabetes: A Public Health Issue. *Canadian Journal of Diabetes*, *44*(6), 549–554. https://doi.org/10.1016/j.jcjd.2020.06.012

Dennick, K., Sturt, J., & Speight, J. (2017a). What is diabetes distress and how can we measure it? A narrative review and conceptual model. *Journal of Diabetes and Its Complications*, *31*(5), 898–911. https://doi.org/10.1016/j.jdiacomp.2016.12.018

Dennick, K., Sturt, J., & Speight, J. (2017b). What is diabetes distress and how can we measure it? A narrative review and conceptual model. *Journal of Diabetes and Its Complications*, *31*(5), 898–911. https://doi.org/10.1016/j.jdiacomp.2016.12.018

Fayed, A., AlRadini, F., Alzuhairi, R. M., Aljuhani, A. E., Alrashid, H. R., Alwazae, M. M., & Alghamdi, N. R. (2022). Relation between diabetes related distress and glycemic control: The mediating effect of adherence to treatment. *Primary Care Diabetes*, *16*(2), 293–300. https://doi.org/10.1016/j.pcd.2021.12.004

Fisher, L., Hessler, D. M., Polonsky, W. H., & Mullan, J. (2012a). When Is Diabetes Distress Clinically Meaningful? *Diabetes Care*, *35*(2), 259–264. https://doi.org/10.2337/dc11-1572

Fisher, L., Hessler, D. M., Polonsky, W. H., & Mullan, J. (2012b). When is diabetes distress clinically meaningful? Establishing cut points for the diabetes distress scale. *Diabetes Care*, *35*(2), 259–264. https://doi.org/10.2337/dc11-1572

García-Sánchez, A., Miranda-Díaz, A. G., & Cardona-Muñoz, E. G. (2020). The Role of Oxidative Stress in Physiopathology and Pharmacological Treatment with Pro- and Antioxidant Properties in Chronic Diseases. *Oxidative Medicine and Cellular Longevity*, *2020*, 1–16. https://doi.org/10.1155/2020/2082145

Giugliano, D., Maiorino, M. I., Bellastella, G., & Esposito, K. (2018). Glycemic control in type 2 diabetes: from medication nonadherence to residual vascular risk. *Endocrine*, *61*(1), 23–27. https://doi.org/10.1007/s12020-017-1517-9

Gómez-Ambrosi, J., Silva, C., Galofré, J. C., Escalada, J., Santos, S., Gil, M. J., Valentí, V., Rotellar, F., Ramírez, B., Salvador, J., & Frühbeck, G. (2011). Body Adiposity and Type 2 Diabetes: Increased Risk With a High Body Fat Percentage Even Having a Normal BMI. *Obesity*, *19*(7), 1439–1444. https://doi.org/10.1038/oby.2011.36

Gurung, M., Li, Z., You, H., Rodrigues, R., Jump, D. B., Morgun, A., & Shulzhenko, N. (2020). Role of gut microbiota in type 2 diabetes pathophysiology. *EBioMedicine*, *51*, 102590. https://doi.org/10.1016/j.ebiom.2019.11.051

Helgeson, V. S., Van Vleet, M., & Zajdel, M. (2020). Diabetes stress and health: Is aging a strength or a vulnerability? *Journal of Behavioral Medicine*, *43*(3), 426–436. https://doi.org/10.1007/s10865-019-00106-4

Hirano, T. (2018). Pathophysiology of Diabetic Dyslipidemia. *Journal of Atherosclerosis and Thrombosis*, *25*(9), 771–782. https://doi.org/10.5551/jat.RV17023

Hirooka, Y. (2020). Sympathetic Activation in Hypertension: Importance of the Central Nervous System. *American Journal of Hypertension*, *33*(10), 914–926. https://doi.org/10.1093/ajh/hpaa074

Hu, X., Yu, W., Yang, L., Pan, W., Si, Q. y. a, Chen, X., Li, Q., & Gu, X. (2019). The Association Between First-Degree Family History of Diabetes and Metabolic Syndrome. *Endocrine Practice*, *25*(7), 678–683. https://doi.org/10.4158/EP-2018-0543

Ismail, L., Materwala, H., & Al Kaabi, J. (2021). Association of risk factors with type 2 diabetes: A systematic review. *Computational and Structural Biotechnology Journal*, *19*, 1759–1785. https://doi.org/10.1016/j.csbj.2021.03.003

Kautzky-Willer, A., Kosi, L., Lin, J., & Mihaljevic, R. (2015). Gender-based differences in glycaemic control and hypoglycaemia prevalence in patients with type 2 diabetes: results from patient-level pooled data of six randomized controlled trials. *Diabetes, Obesity and Metabolism*, *17*(6), 533–540. https://doi.org/10.1111/dom.12449

Khan, R., Chua, Z., Tan, J., Yang, Y., Liao, Z., & Zhao, Y. (2019). From Pre-Diabetes to Diabetes: Diagnosis, Treatments and Translational Research. *Medicina*, *55*(9), 546. https://doi.org/10.3390/medicina55090546

Khurana, L., Durand, E. M., Gary, S. T., Otero, A. V., Dumais, K. M., Beck, J., Zurakowski, D., Hall, C., & Dallabrida, S. M. (2019). Mechanisms for improving diabetes patient–provider communication through optimal use of e-clinical technologies . *Patient Preference and Adherence*, *Volume 13*, 981–992. https://doi.org/10.2147/PPA.S207008

Kim, M. J., Jung, H. S., Hwang-Bo, Y., Cho, S. W., Jang, H. C., Kim, S. Y., & Park, K. S. (2013). Evaluation of 1,5-anhydroglucitol as a marker for glycemic variability in patients with type 2 diabetes mellitus. *Acta Diabetologica*, *50*(4), 505–510. https://doi.org/10.1007/s00592-011-0302-0

Kirk, J. K., & Stegner, J. (2010). Self-Monitoring of Blood Glucose: Practical Aspects. *Journal of Diabetes Science and Technology*, *4*(2), 435–439. https://doi.org/10.1177/193229681000400225

LEE, J., KIM, H.-R., JANG, T.-W., LEE, D.-W., JEONG, C., & KANG, M.-Y. (2020). Poor glycemic control in workers with diabetes mellitus in relation to

long working hours: a cross-sectional study. *Industrial Health*, *58*(5), 451–459. https://doi.org/10.2486/indhealth.2020-0037

Lee, M. (2021). Blood glucose control: Where are we? *Journal of Diabetes Investigation*, *12*(10), 1762–1764. https://doi.org/10.1111/jdi.13632

Levy, N. K., Park, A., Solis, D., Hu, L., Langford, A. T., Wang, B., & Rogers, E. S. (2022). Social Determinants of Health and Diabetes-Related Distress in Patients With Insulin-Dependent Type 2 Diabetes: Cross-sectional, Mixed Methods Approach. *JMIR Formative Research*, *6*(10), e40164. https://doi.org/10.2196/40164

Maddatu, J., Anderson-Baucum, E., & Evans-Molina, C. (2017). Smoking and the risk of type 2 diabetes. *Translational Research*, *184*, 101–107. https://doi.org/10.1016/j.trsl.2017.02.004

Malmström, H., Walldius, G., Grill, V., Jungner, I., Gudbjörnsdottir, S., & Hammar, N. (2014). Fructosamine Is a Useful Indicator of Hyperglycaemia and Glucose Control in Clinical and Epidemiological Studies – Cross-Sectional and Longitudinal Experience from the AMORIS Cohort. *PLoS ONE*, *9*(10), e111463. https://doi.org/10.1371/journal.pone.0111463

Mersha, A. G., Tollosa, D. N., Bagade, T., & Eftekhari, P. (2022). A bidirectional relationship between diabetes mellitus and anxiety: A systematic review and meta-analysis. *Journal of Psychosomatic Research*, *162*, 110991. https://doi.org/10.1016/j.jpsychores.2022.110991

Merz, K. E., & Thurmond, D. C. (2020). Role of Skeletal Muscle in Insulin Resistance and Glucose Uptake. In *Comprehensive Physiology* (pp. 785–809). Wiley. https://doi.org/10.1002/cphy.c190029

Mohamed, S. F., Mwangi, M., Mutua, M. K., Kibachio, J., Hussein, A., Ndegwa, Z., Owondo, S., Asiki, G., & Kyobutungi, C. (2018). Prevalence and factors associated with pre-diabetes and diabetes mellitus in Kenya: results from a national survey. *BMC Public Health*, *18*(S3), 1215. https://doi.org/10.1186/s12889-018-6053-x

Moulton, C. D., Pickup, J. C., & Ismail, K. (2015). The link between depression and diabetes: the search for shared mechanisms. *The Lancet Diabetes & Endocrinology*, *3*(6), 461–471. https://doi.org/10.1016/S2213-8587(15)00134-5

MS, H., NA, I., HM, A., & CG, K. (2019a). Study of the effect of glycemic control on the diabetes-related distress in a sample of Egyptian patients with diabetes mellitus. *Diabetes Updates*, *5*(4). https://doi.org/10.15761/DU.1000134

MS, H., NA, I., HM, A., & CG, K. (2019b). Study of the effect of glycemic control on the diabetes-related distress in a sample of Egyptian patients with diabetes mellitus. *Diabetes Updates*, *5*(4). https://doi.org/10.15761/du.1000134

Muraki, I., Wada, H., & Tanigawa, T. (2018). Sleep apnea and type 2 diabetes. *Journal of Diabetes Investigation*, *9*(5), 991–997. https://doi.org/10.1111/jdi.12823

Murdolo, G., & Smith, U. (2006). The dysregulated adipose tissue: A connecting link between insulin resistance, type 2 diabetes mellitus and atherosclerosis. *Nutrition, Metabolism and Cardiovascular Diseases*, *16*, S35–S38. https://doi.org/10.1016/j.numecd.2005.10.016

Niwaha, A. J., Rodgers, L. R., Greiner, R., Balungi, P. A., Mwebaze, R., McDonald, T. J., Hattersley, A. T., Shields, B. M., Nyirenda, M. J., & Jones, A. G. (2021). HbA1c performs well in monitoring glucose control even in populations with high prevalence of medical conditions that may alter its reliability: the OPTIMAL observational multicenter study. *BMJ Open Diabetes Research & Care*, *9*(1), e002350. https://doi.org/10.1136/bmjdrc-2021-002350

Noman, S. M., Arshad, J., Zeeshan, M., Rehman, A. U., Haider, A., Khurram, S., Cheikhrouhou, O., Hamam, H., & Shafiq, M. (2021). An Empirical Study on Diabetes Depression over Distress Evaluation Using Diagnosis Statistical Manual and Chi-Square Method. *International Journal of Environmental Research and Public Health*, *18*(7), 3755. https://doi.org/10.3390/ijerph18073755

O'Donoghue, G., O'Sullivan, C., Corridan, I., Daly, J., Finn, R., Melvin, K., & Peiris, C. (2021). Lifestyle Interventions to Improve Glycemic Control in Adults with Type 2 Diabetes Living in Low-and-Middle Income Countries: A Systematic Review and Meta-Analysis of Randomized Controlled Trials (RCTs). *International Journal of Environmental Research and Public Health*, *18*(12), 6273. https://doi.org/10.3390/ijerph18126273

Patra, S., Patro, B., Padhy, S., & Mantri, J. (2021). Prevalence of diabetes distress and its relationship with self-management in patients with type 2 diabetes mellitus. *Industrial Psychiatry Journal*, *30*(2), 234. https://doi.org/10.4103/ipj.ipj_60_19

Petersen, M. C., & Shulman, G. I. (2018). Mechanisms of Insulin Action and Insulin Resistance. *Physiological Reviews*, *98*(4), 2133–2223. https://doi.org/10.1152/physrev.00063.2017

Polonsky, W. H., Fisher, L., Earles, J., Dudl, R. J., Lees, J., Mullan, J., & Jackson, R. A. (2005). Assessing Psychosocial Distress in Diabetes. *Diabetes Care*, *28*(3), 626–631. https://doi.org/10.2337/diacare.28.3.626

Powers, M. A., Richter, S. A., Ackard, D. M., & Craft, C. (2017). Diabetes Distress Among Persons With Type 1 Diabetes. *The Diabetes Educator*, *43*(1), 105–113. https://doi.org/10.1177/0145721716680888

Regufe, V. M. G., Pinto, C. M. C. B., & Perez, P. M. V. H. C. (2020). Metabolic syndrome in type 2 diabetic patients: a review of current evidence. *Porto Biomedical Journal*, *5*(6), e101. https://doi.org/10.1097/j.pbj.0000000000000101

Riise, H. K. R., Haugstvedt, A., Igland, J., Graue, M., Søfteland, E., Hermann, M., Carlsson, S., Skinner, T. C., Åsvold, B. O., & Iversen, M. M. (2025). Diabetes distress and associated psychosocial factors in type 2 diabetes. A population-based cross-sectional study. The HUNT study, Norway. *Diabetology & Metabolic Syndrome*, *17*(1), 62. https://doi.org/10.1186/s13098-025-01631-w

Rodbard, D. (2016). Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities. *Diabetes Technology & Therapeutics*, *18*(S2), S2-3-S2-13. https://doi.org/10.1089/dia.2015.0417

Schmitt, A., Reimer, A., Kulzer, B., Haak, T., Ehrmann, D., & Hermanns, N. (2016). How to assess diabetes distress: comparison of the Problem Areas in Diabetes Scale (<scp>PAID</scp>) and the Diabetes Distress Scale (<scp>DDS</scp>). *Diabetic Medicine*, *33*(6), 835–843. https://doi.org/10.1111/dme.12887

Sendekie, A. K., Limenh, L. W., Bizuneh, G. K., Kasahun, A. E., Wondm, S. A., Tamene, F. B., Dagnew, E. M., Gete, K. Y., Kassaw, A. T., Dagnaw, A. D., Tadesse, Y. B., & Abate, B. B. (2025). Psychological distress and its impact on glycemic control in patients with diabetes, Northwest Ethiopia. *Frontiers in Medicine*, *12*. https://doi.org/10.3389/fmed.2025.1488023

Sherwani, S. I., Khan, H. A., Ekhzaimy, A., Masood, A., & Sakharkar, M. K. (2016). Significance of HbA1c Test in Diagnosis and Prognosis of Diabetic Patients. *Biomarker Insights*, *11*, BMI.S38440. https://doi.org/10.4137/BMI.S38440

Shirey, K., Manyara, S. M., Atwoli, L., Tomlin, R., Gakinya, B., Cheng, S., Kamano, J., Laktabai, J., & Pastakia, S. (2015). Symptoms of depression among patients attending a diabetes care clinic in rural western Kenya. *Journal of Clinical & Translational Endocrinology*, *2*(2), 51–54. https://doi.org/10.1016/j.jcte.2015.02.002

Simelane, X., Fina-Lubaki, J.-P., & Francis, J. M. (2025). Epidemiology of hypertension among patients with type 2 diabetes in the Democratic Republic of Congo. *African Journal of Primary Health Care & Family Medicine*, *17*(1). https://doi.org/10.4102/phcfm.v17i1.4712

Skovlund, S. E., & Peyrot, M. (2005). The Diabetes Attitudes, Wishes, and Needs (DAWN) Program: A New Approach to Improving Outcomes of Diabetes Care. *Diabetes Spectrum*, *18*(3), 136–142. https://doi.org/10.2337/diaspect.18.3.136

Spanakis, E. K., & Golden, S. H. (2013). Race/Ethnic Difference in Diabetes and Diabetic Complications. *Current Diabetes Reports*, *13*(6), 814–823. https://doi.org/10.1007/s11892-013-0421-9

Taylor, S. I., Yazdi, Z. S., & Beitelshees, A. L. (2021). Pharmacological treatment of hyperglycemia in type 2 diabetes. *Journal of Clinical Investigation*, *131*(2). https://doi.org/10.1172/JCI142243

Trikkalinou, A., Papazafiropoulou, A. K., & Melidonis, A. (2017). Type 2 diabetes and quality of life. *World Journal of Diabetes*, *8*(4), 120. https://doi.org/10.4239/wjd.v8.i4.120

Uchendu, C., & Blake, H. (2017). Effectiveness of cognitive–behavioural therapy on glycaemic control and psychological outcomes in adults with diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. *Diabetic Medicine*, *34*(3), 328–339. https://doi.org/10.1111/dme.13195

Walker, R. J., Strom Williams, J., & Egede, L. E. (2016). Influence of Race, Ethnicity and Social Determinants of Health on Diabetes Outcomes. *The American Journal of the Medical Sciences*, *351*(4), 366–373. https://doi.org/10.1016/j.amjms.2016.01.008

Wang, G., Liu, X., Ying, Z., Yang, G., Chen, Z., Liu, Z., Zhang, M., Yan, H., Lu, Y., Gao, Y., Xue, K., Li, X., & Chen, Y. (2023). Optimized glycemic control of type 2 diabetes with reinforcement learning: a proof-of-concept trial. *Nature Medicine*. https://doi.org/10.1038/s41591-023-02552-9

Whitebird, R. R., Kreitzer, M. J., Vazquez-Benitez, G., & Enstad, C. J. (2018). Reducing diabetes distress and improving self-management with mindfulness. *Social Work in Health Care*, *57*(1), 48–65. https://doi.org/10.1080/00981389.2017.1388898

Wojujutari Ajele, K., & Sunday Idemudia, E. (2025). The role of depression and diabetes distress in glycemic control: A meta-analysis. *Diabetes Research and Clinical Practice*, *221*, 112014. https://doi.org/10.1016/j.diabres.2025.112014

Xiong, J.-Y., Wang, J.-M., Zhao, X.-L., Yang, C., Jiang, X.-S., Chen, Y.-M., Chen, C.-Q., & Li, Z.-Y. (2021). Glycated albumin as a biomarker for diagnosis of diabetes mellitus: A systematic review and meta-analysis. *World Journal of Clinical Cases*, *9*(31), 9520–9534. https://doi.org/10.12998/wjcc.v9.i31.9520

Zhang, Y.-Y., Li, W., Sheng, Y., Wang, Q., Zhao, F., & Wei, Y. (2024a). Prevalence and Correlators of Diabetes Distress in Adults with Type 2 Diabetes: A Cross-Sectional Study. *Patient Preference and Adherence*, *Volume 18*, 111–130. https://doi.org/10.2147/PPA.S442838

Zhang, Y.-Y., Li, W., Sheng, Y., Wang, Q., Zhao, F., & Wei, Y. (2024b). Prevalence and Correlators of Diabetes Distress in Adults with Type 2 Diabetes: A Cross-Sectional Study. *Patient Preference and Adherence*, *Volume 18*, 111–130. https://doi.org/10.2147/PPA.S442838

APPENDICES

Appendix 1: Study Budget

The projected budget estimate for this study is as below. All the estimated budget will be catered for by the principal investigator

No	Study Items	Quantity	Cost per Unit in Kshs	Total cost
A	**Stationery and Equipment**			
1	Printing papers	10 reams	400	4000
2	Stapler and staples	1 and 1 Pkt respectively	300	600
3	Ball points	1 packet	450	450
4	Pencils	5	30	150
5	Erasers	5	15	60
6	Note books	5	50	250
B	**Development of Proposal**			
7	Printing of drafts	40 pages (x 8 copies)	10/page	3,200
8	Printing & binding final	3 copies	600/copy	1,800
C	**Fieldwork**			
9	Laptop and internet			25000
10	Research assistants	2	15000	30000
11	Biostatistician consultations (statistician/Analysis)	-	-	30000
12	Laboratory (Hba1c testing)	354	600	212,400
13	Questionnaire printing, copies	7 pages (x 200 copies)	2/copy	2,800
14	Printing of draft thesis	60 pages (x 10 copies)	10/page	6,000
15	Final printing & binding (hard)	7 copies	800/ copy	5,600
16	Contingencies (10%)	-		20,000
	Grand Total			**342,310**

Appendix 2: Data Tool

SOCIAL DEMOGRAPHIC CHARACTERISTICS OF TYPE 2 DIABETES PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA.

Study Number: _____ Date: _____

PART A: DEMOGRAPHICS

1. Age (years): _____
2. Sex: _____
3. Marital Status:

   Single____ Married ____ Separated/Divorced____

   Widowed ____

4. Occupational status

   Unemployed ____ Employed ____ Part-time ____ Other ____

5. Insurance status

   Insured ____ Not insured ____

6. Level of Education

   Primary____ Secondary ____ Tertiary____ None____

7. Duration of Diabetes (years): _____

8. Treatment Modality:

   Oral antihyperglycemic agents _____

   Insulin _____

   Insulin + Oral antihyperglycemic agents _____

9. Co- morbidities

   Hypertension: Yes ____ No ____

PART B: PHYSICAL EXAM

10. Weight (Kgs): _____

11. Height (Meters): _____

12. BMI (Kgs/m^2): _____

13. Blood Pressure (mmHg):_____/_____

PART C: GLYCEMIC CONTROL

HBA1C _____

DDS

DIRECTIONS:

Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	**A Slight Problem**	**A Moderate Problem**	**Somewhat Serious Problem**	**A Serious Problem**	**A Very Serious Problem**
1. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
2. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
3. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
4. Feeling angry, scared and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
6. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6

7. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	6
8. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

	Not a Problem	**A Slight Problem**	**A Moderate Problem**	**Somewhat Serious Problem**	**A Serious Problem**	**A Very Serious Problem**
9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
10. Feeling that diabetes controls my life.	1	2	3	4	5	6
11. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

DDS17 SCORING SHEET

INSTRUCTIONS FOR SCORING:

The DDS17 yields a total diabetes distress score plus 4 subscale scores, each addressing a different kind of distress. To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale.

Current research[2] suggests that a mean item score 2.0 – 2.9 should be considered 'moderate distress,' and a mean item score ≥ 3.0 should be considered 'high distress.' Current research also indicates that associations between DDS scores and behavioral management and biological variables (e.g., A1C) occur with DDS scores of ≥ 2.0. Clinicians may consider moderate or high distress worthy of clinical attention, depending on the clinical context.

We also suggest reviewing the patient's responses across all items, regardless of mean item scores. It may be helpful to inquire further or to begin a conversation about any single item scored ≥ 3.

Total DDS Score:

a. Sum of 17 item scores. _____

b. Divide by: _____17_____

c. Mean item score: _____

Moderate distress or greater? (mean item score ≥ 2.0) yes__ no__

A. Emotional Burden:

a. Sum of 5 items (2, 4, 7, 10, 14) _____

b. Divide by: _____5_____

c. Mean item score: _____

Moderate distress or greater? (mean item score ≥ 2.0) yes__ no__

B. Physician Distress:

a. Sum of 4 items (1, 5, 11, 15) _____

b. Divide by: _____4_____

c. Mean item score: _____

Moderate distress or greater? (mean item score ≥ 2.0) yes__ no__

C. Regimen Distress:

a. Sum of 5 items (6, 8, 3, 12, 16) _____

b. Divide by: _____5_____

c. Mean item score: _____

Moderate distress or greater? (mean item score ≥ 2.0)
yes__ no__

D: Interpersonal Distress:

a. Sum of 3 items (9, 13, 17) _____

b. Divide by: _____3_____

c. Mean item score: _____

Moderate distress or greater? (mean item score ≥ 2.0)

yes__ no__

Appendix 3: Informed Consent

Study Title: DIABETES DISTRESS AND ITS CORRELATION WITH GLYCEMIC CONTROL AMONG TYPE 2 DIABETES PATIENTS AT MOI TEACHING AND REFFERAL HOSPITAL, ELDORET, KENYA

Name of Principal Investigator(s): Dr. Imran Mahmud Mohamed

Co-investigator(s): Dr. Jemima Kamano

Name of Organization: Moi University School of Medicine

Address: P.O Box 4606 030100 Telephone Number: +254 53 2033235

Name of Sponsor/Funding Agency: None

Informed Consent Form for: Diabetes Distress Study Participants

This Informed Consent Form has two parts:

• **Part I**: Information Sheet to share information about the study with you

• **Part II**: Certificate of Consent for signatures if you choose to participate

PART I: INFORMATION SHEET

Introduction:

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions.

Taking part in this research study is voluntary. Saying no will not affect your rights to health care or any other services. Your treatment/payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that information provided by you be destroyed under supervision. This would be before data is de-identified and aggregated. You will be notified if new information becomes available about the risks or benefits of this research. You will receive a copy of this form after it is signed

Purpose of the study: This study aims to find the correlation between diabetes distress- a phenomena experienced by people with diabetes and find out its correlation with glycemic control. Information that will be gotten from this study will help us characterize the relationship between the two and aid in policy making in the diabetes management.

Study site: This study is being conducted at the MTRH Diabetes Outpatient Clinic.

Study population: You are eligible to take part in this research study because you are greater than 18 years old, and are enrolled in the MTRH diabetes outpatient clinic for management of diabetes.

Study procedures: This will be a cross-sectional study which means we will complete all study procedures on your day of enrolment in the shortest time possible. We aim to recruit up to 364 participants.

If you agree to participate in the study, the following will be done:

Your social demographic characteristics will be taken and recorded safely.

You will be asked questions using the diabetes distress scale and scored on a likert scale and you will be scored as low, moderate or high distress

Your blood sample will be taken to measure your hba1c level as a marker for glycemic control

Benefits: There may be no direct benefits to you, The study findings will however help clinicians and the hospital at large I coming up with better and broader effective management strategies for type 2 diabetes patients at MTRH.

Risks/Discomforts: We will ensure that high standards are applied during our information collection and avoid exposure to any risks to the study participants during the time of study. The collection of blood for the test will be done by trained professional keeping in line with the standards required for such a procedure

Payments and Reimbursements: No payments or reimbursements will be provided to you for your participation in this study.

Confidentiality: All reasonable efforts will be made to keep your protected information private and confidential. Using or sharing ("disclosure") of such information will follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the use and disclosure of your study information. We may need to share your protected information with the community advisory board, MTRH//MU-IREC, NACOSTI or the healthcare team. We will retain your research records for at least six years after the study is completed. At that time, the research information is destroyed by shredding any paper documents, and deleting any computer records. If you decide to withdraw your permission for use of your personal data, contact Dr. Imran Mahmud in writing and let them know your decision. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality. You have the right to see and

copy your personal information related to the research study for as long as the study team holds this information

Compensation for injury:

We do not anticipate that any injury may occur to you resulting from participating in this study.

PART II: CONSENT OF PATICIPANT

I have read or have had someone read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks, discomfort, and possible benefits (if any) of the study. I freely volunteer to take part in this study.

[If the participant is illiterate, or for some reason is unable to write, they should provide a thumbprint and a competent witness must be engaged during the consent process]

_____	_____	_____
Name of Participant	Signature of participant /Thumbprint	Date & Time
_____	_____	_____
Name of Witness [Optional]	Signature of Witness	Date & Time
_____	_____	_____
Name of the person obtaining consent	Signature of person obtaining consent	Date & Time
Dr. Imran Mahmud	_____	_____
Printed name of the Principal Investigator	Signature of Investigator	Date & Time

Contacts for questions about the study

Questions about the study: Dr. **Imran Mahmud** Phone: **0707150344**

Email: imranajahdhmy@gmail.com

Questions about your rights as a participant: You may contact the Institutional Ethics and Research Committee (MTRH//MU-IREC) 0787723677 or email irec@mtrh.go.ke or irecoffice@gmail.com. The MTRH//MU-IREC is a group of people that review studies for safety and to protect the rights of participants.

FOMU YA KIBALI ILIYOARIFIWA

Anwani Ya Utafiti: MSONGO WA MAWAZO KUHUSU KISUKARI NA UHUSIANO WAKE NA UDHIBITI WA KISUKARI KATI YA WAGONJWA WA KISUKARI AINA YA 2 KATIKA HOSPITALI YA MAFUNZO NA RUFAA YA MOI, ELDORET, KENYA

Jina la Mchunguzi Mkuu: Dkt. Imran Mahmud

Wachunguzi wenza: Dkt. Jemima Kamano, Prof Benson Gakinya

Jina la Shirika: Chuo Kikuu cha Moi-Shule ya Matibabu

Anwani: Sanduku la Posta 4606 030100 Nambari ya Simu: +254 53 2033235

Jina la Mfadhili/Wakala wa Ufadhili: Hakuna

Fomu ya Kibali ya: Kuzingatia Tiba ya Endocrine kwa wagonjwa wa Kipokezi cha Homoni wanaoishi na Saratani ya Matiti MTRH

Hii Fomu ya Kibali ina sehemu mbili:

• **Sehemu ya I**: Karatasi ya Habari [kushiriki habari na wewe kuhusu utafiti]

• **Sehemu ya II**: Cheti cha Kibali [ya saini ikiwa utachagua kushiriki]

SEHEMU YA I: KARATASI YA HABARI

Utangulizi:

Unaulizwa kushirika katika somo la utafiti. Taarifa hii inapeanwa kukuambia kuhusu utafiti. Tafadhali soma fomu hii kwa makini. Utapewa nafasi kuuliza maswali.

Kushiriki katika huu utafiti ni kwa hiari. Kusema hapana haitaathiri haki zako kwa huduma ya afya au huduma zingines. Matibabu yako/malipo au kujiandikisha kwa mpango yoyote ya afya au kustahiki kwa manufaa haitaathiriwa ikiwa utaamua kutoshiriki. Pia uko huru kujiondoa kutoka kwa utafiti huu wakati wowote. Ikiwa baada ya ukusanyaji wa data utaamua kujiondoa, unaweza omba kwamba taarifa uliyopeana yaharibiwe chini ya usimamizi. Hii itafanyika kabla ya data kutotambuliwa na kujumlishwa. Utajulishwa ikiwa habari mpya inapatikana kuhusu hatari au manufaa ya utafitu huu. Utapokea nakala ya fomu hii baada ya kutiwa saini

Madhumuni ya utafiti: Tafiti hii inalenga kupata uhusiano kati ya msongo wa mawazo wa kisukari - jambo linaloathiri watu wenye kisukari, na kugundua uhusiano wake na udhibiti wa kiwango cha sukari mwilini. Taarifa ambazo zitapatikana kutoka tafiti hii zitasaidia kutambua uhusiano kati ya mambo hayo mawili na kuchangia katika kutengeneza sera za kusimamia kisukari.

Eneo la Utafiti: Utafiti huu unafanyika katika kliniki ya ugonjwa wa kisukari ya MTRH.

Idadi ya Watu kwa Utafiti:

Unastahili kushiriki katika somo hili la utafiti kwa sababu wewe ni mkubwa zaidi ya miaka 18, na umejiandikisha katika kliniki ya saratani ya MTRH kwa ajili ya usimamizi wa matatizo ya saratani.

Utaratibu wa Utafiti:

Hii itakuwa utafiti wa sehemu mbali mbali ambayo inamaanisha tutakamilisha taratibu zote za masomo katika siku yako ya usajili kwa muda mfupi iwezekanavyo. Tunalenga kuandikisha hadi washiriki 364.

Ikiwa utakubali kushiriki katika utafiti huu, utafanya yafuatayo:

Wafanyakazi wa utafiti

Manufaa:

Hautaweza kupata manufaa yoyote ya moja kwa moja kutoka kwa utafiti..

Hatari/Usumbufu:

Tutakuwa tunakusanya habari ya afya na demografia ya jamii ambayo ni sehemu ya mambo ya kila siku ya huduma.

Malipo na Marejesho:

Hakuna malipo au marejesho yatakayotolewa kwako kwa ushiriki wako katika utafiti huu.

Usiri:

Jitihada zinazowezekana zitafanywa ili kuweka habari yako iliyolindwa ya kibinafsi na ya siri. Kutumia au kushiriki ("ufichuzi") ya habari hiyo itafuata miongozo ya kibinafsi ya Kitaifa. Kwa kusaini hati ya idhini ya utafiti huu, unatoa ruhusa ("idhini") kwa matumizi na ufichuzi wa maelezo yako ya utafiti. Tunaweza kuhitaji kushiriki maelezo yako yaliyolindwa na bodi ya ushauri wa jamii, MTRH / / MU-IREC, NACOSTI au timu ya huduma ya afya. Tutahifadhi rekodi zako za utafiti kwa angalau miaka sita baada ya utafiti kukamilika. Kwa wakati huo, habari za utafiti huharibiwa kwa kukatakata karatasi yoyote, na kufuta rekodi zozote za kompyuta. Ukiamua kuondoa ruhusa yako ya matumizi ya data yako ya kibinafsi, wasiliana na Dkt. Imran Mahmud kwa maandishi na uwajulishe uamuzi wako. Wakati huo, tutaacha ukusanyaji zaidi wa habari yoyote kukuhusu. Hata hivyo, taarifa za afya

zilizokusanywa kabla ya kujiondoa huu zinaweza kuendelea kutumika kwa madhumuni ya kutoa taarifa na ubora wa utafiti. Una haki ya kuona na kunakili maelezo yako ya kibinafsi kuhusiana na somo la utafiti kwa muda mrefu kama timu ya utafiti inashikilia habari hii

Fidia kwa majeraha:

Hatutarajii jeraha lolote litatokea kwako kutokana na kushiriki katika utafiti huu.

SEHEMU YA II: IDHINI YA MSHIRIKI:

Nimesoma au mtu amenisomea maelezo ya somo la utafiti. Mchunguzi au mwakilishi wake amenielezea utafiti kwangu na amejibu maswali yangu yote niliyonayo kwa wakati huu. Nimeambiwa hatari zinazowezekana, usumbufu na faida zinazowezekana (ikiwa kunayo) ya utafiti. Najitolea kwa hiari kushiriki katika utafiti huu.

[Ikiwa mshiriki hajasoma, au kwa sababu fulani hawezi kuandika, wanafaa kupeana kidole gumba na shahidi mwenye uwezo lazima wahusishwe kwa mchakato wa kibali]

_____	_____	_____
Jina la Mshiriki	Saini ya mshiriki/Kidole Gumba	Tarehe na Saa
_____	_____	_____
Jina la Shahidi [Hiari]	Saini ya Shahidi	Tarehe na Saa
_____	_____	_____
Jina la mtu anayetafuta Idhini	Saini ya mtu anayetafuta idhini	Tarehe na Saa
Daktari Imran Mahmud Jina lililochapishwa la mchunguzi	_____ Saini ya Mchunguzi	_____ Tarehe na Saa

Maelezo ya mawasiliano kwa maswali kuhusu utafiti

Maswali kuhusu utafiti: Daktari **Imran Mahmud** Simu: **0707150344**

Barua pepe: **imranjahadhmy@gmail.com**

Maswali kuhusu haki zako kama mshiriki: Unaweza kuwasiliana na Kamati ya Kitaasi ya Maadili na Utafiti (MTRH//MU-IREC) 0787723677 au barua pepe irec@mtrh.go.ke au irecoffice@gmail.com. The MTRH//MU-IREC ni kikundi cha watu wanaohakiki utafiti kwa usalama na kulinda haki za washiriki

Appendix 4:IREC Approval

MTRH/MU-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/678/2023
Approval Number: 0004651

3rd January, 2024

Dr. Imran Mahmud Mohamed,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Mohamed,

DIABETES DISTRESS AND ITS CORRELATION WITH GLYCEMIC CONTROL AMONG TYPE 2 DIABETES PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

This is to inform you that ***MTRH/MU-IREC*** has reviewed and approved the above referenced research proposal. Your application approval number is ***FAN: 0004651.*** The approval period is **3rd January, 2024 – 2nd January, 2025.**
This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MTRH/MU-IREC.***
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MTRH/MU-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MTRH/MU-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from ***MOH at the recommendation of NACOSTI*** for each batch of shipment.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MTRH/ MU-IREC.***

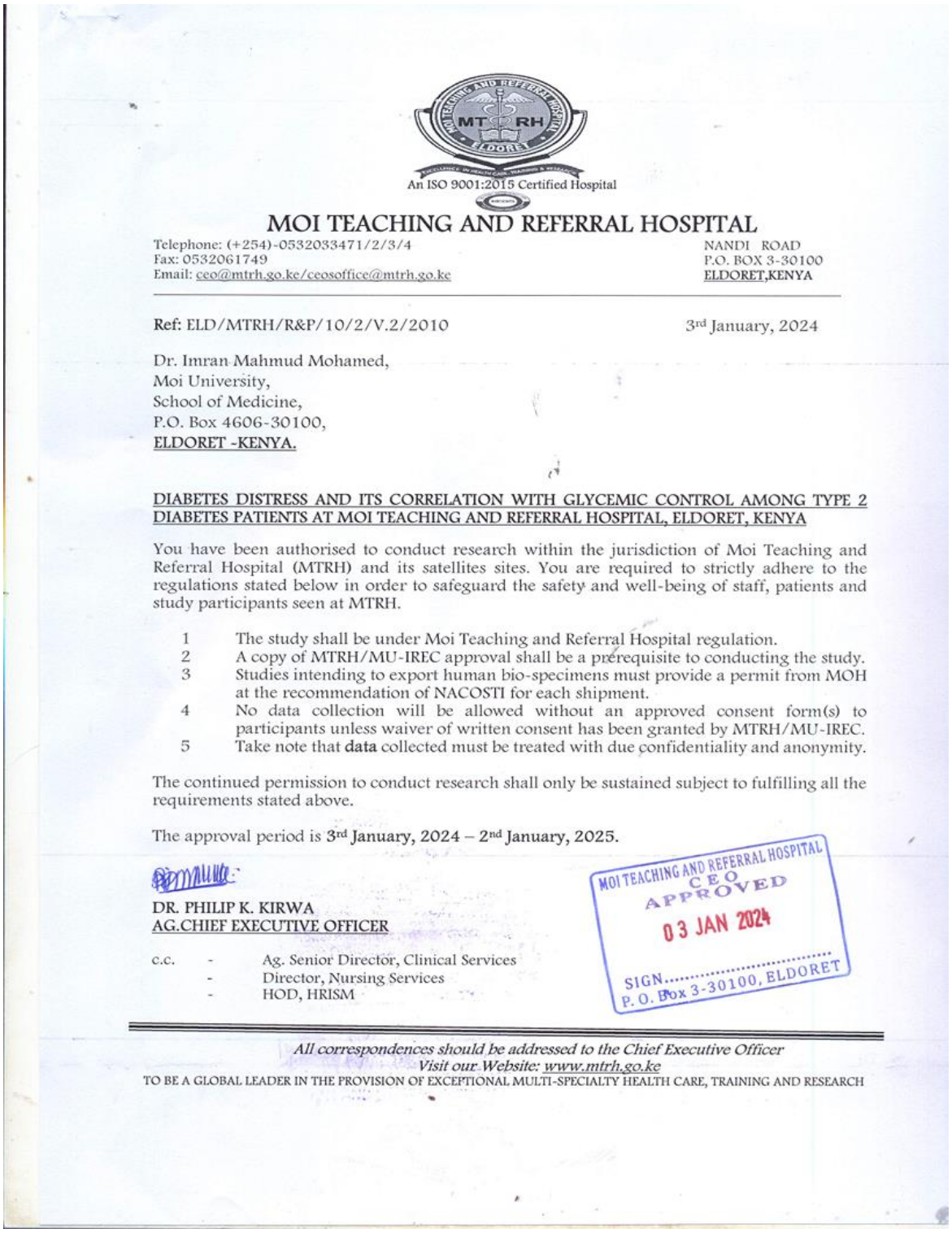
Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital and its satellites sites.

MTRH INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
03 JAN 2024
APPROVED

Sincerely,

PROF. F. WERE

Appendix 5: Moi Teaching and Referral Hospital Approval



An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: (+254)-0532033471/2/3/4
Fax: 0532061749
Email: ceo@mtrh.go.ke/ceosoffice@mtrh.go.ke

NANDI ROAD
P.O. BOX 3-30100
ELDORET,KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

3rd January, 2024

Dr. Imran Mahmud Mohamed,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET -KENYA.

DIABETES DISTRESS AND ITS CORRELATION WITH GLYCEMIC CONTROL AMONG TYPE 2 DIABETES PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

You have been authorised to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) and its satellites sites. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff, patients and study participants seen at MTRH.

1. The study shall be under Moi Teaching and Referral Hospital regulation.
2. A copy of MTRH/MU-IREC approval shall be a prerequisite to conducting the study.
3. Studies intending to export human bio-specimens must provide a permit from MOH at the recommendation of NACOSTI for each shipment.
4. No data collection will be allowed without an approved consent form(s) to participants unless waiver of written consent has been granted by MTRH/MU-IREC.
5. Take note that **data** collected must be treated with due confidentiality and anonymity.

The continued permission to conduct research shall only be sustained subject to fulfilling all the requirements stated above.

The approval period is 3rd January, 2024 – 2nd January, 2025.

DR. PHILIP K. KIRWA
AG.CHIEF EXECUTIVE OFFICER

MOI TEACHING AND REFERRAL HOSPITAL
CEO
APPROVED
03 JAN 2024
SIGN.....
P. O. Box 3-30100, ELDORET

c.c. - Ag. Senior Director, Clinical Services
- Director, Nursing Services
- HOD, HRISM

All correspondences should be addressed to the Chief Executive Officer
Visit our Website: www.mtrh.go.ke
TO BE A GLOBAL LEADER IN THE PROVISION OF EXCEPTIONAL MULTI-SPECIALTY HEALTH CARE, TRAINING AND RESEARCH

Appendix 6: NACOSTI Approval

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **904566**

Date of Issue: **06/March/2025**

RESEARCH LICENSE

This is to Certify that Dr.. IMRAN MAHMUD MOHAMED of Moi University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Uasin-Gishu on the topic: DIABETES DISTRESS AND ITS CORRELATION WITH GLYCEMIC CONTROL AMONG TYPE 2 DIABETES PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA. for the period ending : 06/March/2026.

License No: **NACOSTI/P/25/416268**

904566

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions