

**KAIRUKI UNIVERSITY**  
**SCHOOL OF MEDICINE**  
**DEPARTMENT OF INTERNAL MEDICINE**



**CLINICO BIOCHEMICAL INDICATORS OF KIDNEY DISEASE AMONG NEWLY  
DIAGNOSED DIABETES MELLITUS TYPE 2 ADULTS ATTENDING  
DIABETIC CLINICS IN DAR ES SALAAM.**

**By**

**Consolata D. Kakoko (HK/PG/IM/21/0015)**

**SUPERVISOR: PROF Y. MGONDA**

**CO SUPERVISOR: DR WARLES CHARLES AND DR ALICE GWAMBEGU**

**A Dissertation Submitted in (partial) Fulfillment of the Requirements for the  
Degree of Masters of Medicine (Internal Medicine) at  
Kairuki University**

**2024**

**CERTIFICATION**

The undersigned certifies that he has read and at this moment recommended for submission a Dissertation entitled "***Clinico-Biochemical Indicators of Kidney Disease Among Newly Diagnosed Diabetes Mellitus Type 2 Adults Attending Diabetic Clinics In Dar Es Salaam***" in partial fulfillment of the degree of Masters of Medicine in Internal Medicine of Kairuki University.

Supervisor's signature ..... Date .....

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## **DEDICATION**

This work has been dedicated to my beloved father, Eng. Deusdedit C.V. Kakoko for his unwavering love and support which have been my anchor.

## **ABSTRACT**

**Background:** Kidney disease affects the functionality and structure of the kidney or both. It is the highest cause of mortality among diabetic mellitus patients. Diabetes mellitus type 2, has a long asymptomatic period of hyperglycemia, whereby long-standing hyperglycemia leads to activation and changes of metabolic pathways, which causes dysfunction of renal and vascular cells. Kidney disease is present in about half of patients with DM type 2. Despite diabetes mellitus being discussed as the leading cause of kidney disease, there has been a paucity of information in Dar es Salaam on clinico-biochemical indicators of kidney disease among newly diagnosed DM 2 adults. These indicators include urine protein(albuminuria) as well as serum creatinine which is used in the estimation of glomerular filtration rate. The study findings are expected to show the burden of kidney disease among newly diagnosed DM 2 adult patients in Dar es Salaam, hence emphasizing early detection of kidney disease during diagnosis of DM 2 adults, to avoid poor renal outcomes at a later stage.

**Objective:** To determine the pattern of clinical biochemical indicators of kidney disease among newly diagnosed diabetes mellitus type 2 adults in Dar es Salaam.

**Methodology:** This cross-sectional design study was conducted among newly diagnosed type 2 patients in the public regional referral hospitals in Dar es Salaam city. Random sampling was used to select 380 newly diagnosed type 2 diabetic patients. The study's dependent variable was kidney disease, the composite variable of eGFR and UACR. Independent variables were social demographics such as age, gender, education level, and occupation. Also, risk factors such as history of smoking and drinking alcohol, family history of diabetes, and kidney disease. Data analysis was done using SPSS version 28. Continuous variables were summarized

using mean and standard deviations, while categorical variables were summarized using absolute count and percentage. The categorical comparisons of predictors variables of kidney disease (eGFR and UACR) were made using the chi-square test of independence. The variables that achieved a statistical significance of 0.2 were collectively analyzed in a multivariable logistic regression. A significance level of 0.05 at 95% CI was considered statistically significantly associated with kidney disease (eGFR and UACR).

**Results:** Of the 380 participants recruited, 203(53.4%) were females 177(46.6%) were males and the mean age was  $57.2 \pm 13.0$  standard deviation years. The average serum creatinine level was  $90.6 \pm 35.5$  standard deviation, with an eGFR of  $71.6 \pm 23.4$  standard deviation. The median UACR was 14.0. Among the study participants, 110(28.9%), had an eGFR of less than 60. About 85 participants (22.4%) had a UACR of greater than 30. About 83 participants (21.8%), had both UACR of greater than 30 and eGFR of less than 60. Kidney disease increased with age, mostly observed among participants older than 60. The proportion of KD was most common among divorced and widowed marital groups. The occurrence of KD increased with BMI, with the majority being 25-29.9 and 30+, with relatively equal proportions. The distribution of KD diagnosis was similar between hyperglycemic and non-hyperglycemic patients and was typical among those with a history of alcohol and smoking. Females had a higher proportion of kidney disease compared to males, however, multivariable regression has shown that being female was associated with a lower risk of kidney disease ( $p < 0.05$ ).

**Conclusion:** Clinico-biochemical indicators of kidney disease among newly diagnosed DM 2 adult patients included reduced estimated glomerular filtration rate to

<60mL/min/1.73m<sup>2</sup> and increased UACR> 30mg/g. In this study, there were more study participants with reduced estimated glomerular filtration rate to <60mL/min/1.73m<sup>2</sup> than those with increased UACR> 30mg/g. Moreover, the study findings show that, despite females having a higher proportion of clinico-biochemical indicators of kidney disease than males, they have a lower risk of developing kidney disease.

**Recommendation:** Healthcare providers are emphasized on early screening of clinico-biochemical indicators of kidney disease during the diagnosis of diabetes mellitus type 2 in adult patients. This includes screening both serum creatinine to obtain an estimated glomerular filtration rate and for albuminuria, since DM type 2 asymptomatic patients may develop both or one among the 2 clinico-biochemical indicators. Also regular monitoring of these clinico-biochemical indicators of kidney disease in short intervals during follow-up of the DM 2 patients attending diabetic clinics.

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## **LIST OF ABBREVIATIONS**

ACEI	Angiotensin converting enzymes inhibitors.
ACR	Albumin creatinine ratio
AER	Albumin excretion rate
AGEs	Advanced glycation end products
AKD	Acute kidney diseases
AKI	Acute Kidney injury
ARB	Angiotensin receptor blockers
BPH	Benign prostate hyperplasia
BUN	Blood urea nitrogen
CKD	Chronic kidney disease
DM 2	Diabetes mellitus type 2
DM	Diabetes mellitus
DPP4	Dipeptidyl peptidase 4
eGFR	Estimated glomerular filtration rate.
ESRD	End stage renal disease
GLP	Glucagon like peptides
KDIGO	Kidney Disease Improving Global Outcome
NKD	No known kidney disease

KD	Kidney disease
RRT	Renal replacement therapy
Scr	Serum creatinine

## **DEFINITION OF TERMS**

**Diabetes mellitus:** A group of metabolic disorders characterized by chronic hyperglycemia resulting from defects in insulin secretion, insulin action, or both<sup>1</sup>

**Diabetes mellitus type 2:** Metabolic disorder characterized by hyperglycemia as a result of progressive resistance to normal insulin and or gradual loss of capacity of the body to produce enough insulin action<sup>2</sup>

**Newly diagnosed adult with diabetes mellitus type 2:** Patient aged 18 years and above who has just been recently diagnosed with diabetes mellitus type 2 on immediate visit and has not started on anti-diabetic medications.

**Kidney disease:** A disorder that affects functionality and structure of the kidney or both<sup>3</sup>

## **CHAPTER ONE**

### **1.0 INTRODUCTION**

#### **1.1 BACKGROUND**

##### **1.1.1 Diabetes mellitus**

This is a group of common metabolic disorders characterized by hyperglycemia due to impairment of the body's response to insulin<sup>4</sup>. This may occur due to the pancreas' inability to produce sufficient insulin (Insulin secretion) and the body's inability to effectively utilize the insulin produced (insulin action) or both.<sup>1</sup> DM type 2 is the most common form described by, the body's progressive resistance to regular insulin and or gradual loss of capacity to produce enough insulin action.<sup>4</sup> WHO Classifies types of diabetes mellitus in action-pathology as shown in the appendix.

##### **1.1.2 Epidemiology of Diabetes Mellitus Type 2**

Globally, about 537 million adults aged 20-79 live with diabetes mellitus. This represents 10.5% of the world's population in this age group.<sup>5</sup> DM type 2 is responsible for more than 90% of DM mellitus cases<sup>6</sup>. This is associated with an increase in risk factors like being overweight, physical inactivity, diet modifications, smoking, and increased alcohol consumption.<sup>7</sup> The most significant rise in global prevalence is in low- and middle-income countries compared to high-income countries.<sup>1</sup> Demographic, socio-cultural and economic transitions cause this.<sup>5</sup> About 1.5 million deaths are diabetes attributed yearly.<sup>8</sup> A study done in 2021 reports that about 24 million adults are living with diabetes mellitus in Africa, with about 416,000 deaths attributable to diabetes mellitus.<sup>9</sup> In 2021, the prevalence of diabetes mellitus type 2 adults in Tanzania was estimated to be 12.3%, with an increase from 2.8% in

2011.<sup>5</sup> In 2017, a cross-sectional study done in Morogoro reported that, overall prevalence of DM 2 is 10.08% among newly diagnosed town and adult outpatients. Age, alcohol consumption and being overweight are significant risk factors.<sup>7</sup>

### **1.1.3 Clinical Features of Diabetes Mellitus Type 2**

DM 2 may present with characteristic symptoms, including increased urination, thirst, hunger, weight loss, and blurring of vision.<sup>1</sup> Severe clinical manifestations may include a non-ketotic hyperosmolar state that may result in dehydration and coma. <sup>2</sup> The symptoms may not be severe or absent due to the slow hyperglycemia worsening pace.<sup>1</sup> As a result, one may present with complications during diagnosis.<sup>1</sup>

### **1.1.4 Diagnosis of Diabetes Mellitus Type 2**

According to the WHO and American diabetic association, criteria recommended for diagnosis of diabetes mellitus type 2 include the following: Symptoms of diabetes plus random blood glucose concentration  $\geq 11.1$ mmol/L or in the absence of unequivocal hyperglycemia and acute metabolic decompensation Fasting plasma glucose  $\geq 7.0$ mmol/L or two-hour plasma glucose  $\geq 11.1$ mmol/L during oral glucose tolerance test,<sup>1,2</sup> using a glucose load which contains the equivalent of 75g anhydrous glucose dissolved in water(although not recommended as part of routine care) may be done. These tests should be repeated on a different day for confirmation.<sup>1,2,10</sup> Glycated hemoglobin (HbA1c)  $\geq 6.5\%$  (48mmol/mol) may be used as a follow up test.<sup>1,10</sup>

### **1.1.5 Treatment of Diabetes Mellitus Type 2**

Improving glycemic control is the mainstay of treatment and lowers the risk of complications. Therapy goals should be individualized based on age, social support,

lifestyle, and other pre-existing medical conditions. Also, the patient's ability to understand and comprehend treatment regimens, the presence and severity of complications of diabetes mellitus, and the ability to recognize hypoglycaemia.<sup>2</sup> Principles of diabetes mellitus management include Non-pharmacological and pharmacological measures. These include a healthy lifestyle such as a healthy diet, physical activities, avoidance of tobacco use and harmful alcohol consumption.<sup>8</sup> Also, use of medications for blood glucose control, including parenteral glucose-lowering therapies such as insulin, GLP-1 agonist (exenatide), amylin agonist (pramlintide). Use of Oral hypoglycemic agents such as biguanides (metformin),  $\alpha$ -Glucosidase inhibitors (acarbose), DPP4 inhibitors (sitagliptin), sulfonylurea (glimepiramide), thiazolidinediones (pioglitazone).<sup>2</sup> For severe obesity-related type 2 diabetes, energy restriction through bariatric (metabolic) surgery to reduce the size of the stomach is also established as an effective treatment<sup>9</sup>. The international diabetes federation and the American diabetic association of Clinical Endocrinology have suggested that the A1C goal should be  $\leq 6.5\%$  in most individuals, and there is no lower limit in reducing diabetes-specific complications.<sup>1,2,9,10</sup>

### **1.1.6 kidney disease**

A *kidney disease* is a disorder that affects the functionality and structure of the kidney or both.<sup>3</sup> It has a substantial global growth driven by a complex interaction of communicable and non-communicable diseases, including diabetes mellitus, among the leading etiological factors.<sup>11</sup> Other causes include glomerular diseases, interstitial kidney diseases, infectious diseases, genetic kidney disorders such as polycystic kidney disease, and systemic inflammatory diseases such as systemic lupus erythematosus.<sup>2</sup> Kidney disease risks are influenced by ethnicity, gender, location and

lifestyle.<sup>11</sup> Often, kidney disease has few symptoms until later in the course of the disease when the kidneys are badly damaged.<sup>3</sup> In the presence of symptoms, they are often nonspecific, and there are few kidney-specific clinical events, such as reduced urine output. Laboratory measures are often used to define significant kidney clinical syndrome. These include serum creatinine levels, which are used to calculate estimated GFR based on age, sex, race, and body weight, which grades the stage of kidney disease. Urine tests may be favourable for blood and protein. The urine albumin test is a specific protein test for renal dysfunction, and the urine albumin-to-creatinine ratio (UACR) is used to assess kidney disease among high-risk people who develop it without symptoms.<sup>2</sup> The duration of the kidney disease is also used to specify the diagnosis.<sup>3</sup> The KDIGO definitions, classifications, and grades of kidney diseases, based on laboratory, clinical findings, and duration, are the mainstay to the diagnosis of specific types of kidney disease in 2013,<sup>3</sup> KDIGO classified kidney disease as follows in the appendix.

### **1.1.7 Epidemiology of Kidney Diseases.**

The global burden of kidney disease is increasing, with about 3.16 million deaths in 2019.<sup>12</sup> The burden of Kidney disease is reported higher in lower and mid-income countries as compared to developed countries. The sub-Saharan countries are reported to be most affected.<sup>13</sup> Significant challenges of kidney disease in Africa include high prevalence, delayed presentation, treatment cost, and a general lack of preventive measures.<sup>14</sup> Kidney diseases are among the significant contributors to cardiovascular diseases and mortality in Tanzania as well as other low and middle-income countries.<sup>13</sup> A study done in Bugando Medical Centre reported 27.5% renal dysfunction among 637 adult medical patients from October 2013 to March 2014.<sup>15</sup> A

prospective cohort study conducted at Muhimbili National Hospital in Tanzania from September 2017 to February 2018 reported renal failure of 8.8% among 3013 screened patients, of which 71 had AKI and 195 had CKD.<sup>16</sup>

### **1.1.8 kidney disease in Diabetes Mellitus Type 2**

This is a decline in renal function in people with DM type 2, characterized by increased urine albumin excretion rate and low estimated glomerular filtration rate.<sup>17</sup> The kidney is a frequent target organ of microvascular damage in diabetes mellitus.<sup>18</sup> Currently, DM type 2 is the world's leading cause of kidney disease, which results in end-stage renal disease and consequently requires renal replacement therapy.<sup>19</sup>

### **1.1.9 Epidemiology of Kidney Disease among Patients with Diabetes Mellitus Type 2.**

Kidney disease is present in about half of patients with DM type 2. There is a global, rapid growth of kidney disease in DM type 2, which is a result of the type 2 DM epidemic combined with an increase in the life span of diabetic patients due to better management modalities and control of complications.<sup>19</sup> The increased proportion of CKD caused by diabetes mellitus is seen in developed and developing countries.<sup>19</sup> The prevalence of CKD among patients with diabetes mellitus varies in countries around the world; It is about 27% in China.<sup>18</sup> In Europe, the prevalence of CKD is 2-5 times higher in patients with type 2 DM compared to those without. In low-income countries such as Uganda, the prevalence of CKD ranges from 2-7% in the general population, and of all patients admitted with CKD, 16% have DM.<sup>18</sup> In Tanzania, the prevalence of CKD is 84% among DM type 2 patients.<sup>18</sup>

There is a lower incidence of kidney disease among patients with DM type 1 than those with DM 2. This is caused by several factors, including younger age and healthier at diagnosis as well as fewer comorbidities among DM type 1 patients compared to DM type 2 patients.<sup>18</sup>

#### **1.1.10 Pathophysiology of Kidney Disease in Diabetes Mellitus Type 2.**

Pathogenesis of kidney disease in DM type 2 is related to hyperglycemia like other diabetic microvascular complications.<sup>1,2,18,20</sup> Mechanisms of DM type 2 leading to kidney disease and eventually ESRD are incompletely defined<sup>18</sup>. However, the well-known includes effects of soluble factors (such as growth factors, angiotensin II, endothelin, and AGEs), hemodynamic alterations in renal microcirculation (glomerular hyperfiltration or hyperperfusion, increased glomerular capillary pressure), and changes in the structure of glomerulus (due to increased extracellular matrix, basement membrane thickening, mesangial expansion, fibrosis).<sup>17,21</sup> Glomerular hyperperfusion and renal hypertrophy occur in the first years of DM type 2 and are associated with increased GFR.<sup>2,17</sup> In the first five years of DM type 2, the glomerular basement membrane thickens, and glomerular hypertrophy and mesangial volume expansion occur as GFR returns to normal. After 5-10 years, renal dysfunction increases, and DM type 2 patient begins to excrete small amounts of albumin in urine, which increases in severity with further renal damage.<sup>17</sup> Once macro albuminuria is present, there is a decrease in GFR, and about 50% of individuals reach ESRD within 7 years.<sup>2,17</sup> Blood pressure increases slightly, and the pathological changes are irreversible.<sup>2,17,22</sup>

### **1.1.11 Clinical Features of Kidney Disease in Diabetes Mellitus Type 2.**

Symptoms and signs are unlikely with early kidney disease in diabetes mellitus type 2 but tend to develop as the kidney disease progresses.<sup>17</sup> The symptoms and signs are nonspecific and result from physiological changes caused by kidney damage. These include fluid retention, which results in puffiness around the eyes, lower limb edema, dry and itchy skin, nausea or vomiting caused by uremia, paleness, and fatigue due to anemia.<sup>2,25</sup> As kidney function declines, various other complications occur, such as calcium and phosphate imbalance, which causes bone thinning and fractures.<sup>2,25</sup>

### **1.1.12 Diagnosis of Kidney Disease in Diabetes Mellitus Type 2**

Kidney disease in DM type 2 is diagnosed when the urine albumin levels are increased without any other apparent cause, such as decreased renal function in a diabetes type 2 patient.<sup>2,3,18</sup> Urine albumin creatinine ratio and estimation of GFR are used to diagnose kidney disease in DM type 2 patients.<sup>2,3</sup> To diagnose, there should be the presence of persistent elevated urinary albumin to creatinine ratio  $\geq 30\text{mg/g}$  and decreased estimated GFR  $< 60 \text{ mL/min per } 1.73 \text{ m}^2$  in an individual with DM 2.<sup>18</sup>

### **1.1.13 Treatment of Kidney Disease in Diabetes Mellitus Type 2**

Treatment of kidney disease in diabetes mellitus type 2 targets multiple risk factors to improve kidney outcomes. These include lifestyle interventions such as a healthy diet, physical exercise to control obesity, smoking cessation, and pharmacological and surgical management to achieve glycemic control.<sup>2</sup> Recent studies suggest using sodium-glucose co-transporter two inhibitors and incretin pathway target agents as glucose-lowering agents, which improves kidney outcomes in patients with DM type

2.<sup>18</sup> Treatment of other complications associated with kidney diseases in diabetes mellitus type 2, such as cardiovascular changes, including hypertension, are treated with ARB or ACEI, and rapid treatment of dyslipidemia is of massive contribution to improving renal function.<sup>2,17,18,24</sup>

## **1.2 Problem Statement**

Kidney disease is present in about half of patients with DM type 2<sup>19</sup>. It is the most common cause of ESRD, resulting in significant morbidity and mortality<sup>25</sup>. Associated risk factors of kidney disease in DM type 2 include older age, kidney disease family history, presence of comorbidities such as hypertension, longer duration of untreated DM 2, and obesity<sup>26</sup>. Kidney disease is one of the most burdensome and expensive long-term complications in diabetic type 2 patients<sup>18</sup>.

Most patients will have developed complications, including kidney disease, by the time of diagnosis of diabetes mellitus type 2.<sup>27</sup> Kidney disease is often asymptomatic during DM 2 diagnosis and may not be detected early enough for clinical intervention.<sup>2</sup> Consequently, patients may develop ESRD, which is a devastating medical, social, and economic problem.<sup>25</sup> These patients require renal replacement therapy such as dialysis and renal transplant.<sup>18</sup> Renal replacement therapy is still scarce among patients who need it, especially in Sub-Saharan Africa, including Tanzania.<sup>14</sup>

Early changes occurring as markers of kidney disease among newly diagnosed adults with DM 2 include microalbuminuria and changes in urine output.<sup>2,17,24</sup> These pathophysiological changes of renal function caused by DM 2 result in electrolyte and

biochemical disturbances such as elevation of serum creatinine, thus reducing the glomerular filtration rate.<sup>2,24</sup>

In Tanzania, the prevalence of chronic kidney disease (CKD) among patients with type 2 diabetes mellitus (DM) is 84%. Despite diabetes mellitus being discussed as the leading cause of kidney disease,<sup>18</sup> there has been a lack of information in Dar es Salaam on clinico-biochemical indicators of kidney disease among newly diagnosed DM 2 adults. These indicators include urine protein(albuminuria) and serum creatinine, which are used to estimate the glomerular filtration rate. Thus, this study is expected to identify of distribution of clinical biochemical indicators of kidney disease among newly diagnosed DM 2 adults in Dar es Salaam, including frequency of albuminuria, estimated glomerular filtration rate and risk factors of kidney disease, by social demographic characteristics such as gender, age, marital status and level of education. Therefore, the study findings are expected to show the burden of kidney disease among newly diagnosed DM 2 adult patients in Dar es Salaam, hence emphasizing early detection of kidney disease during diagnosis of DM 2 adults to avoid poor renal outcomes at a later stage such as ESRD.

### **1.3 Rationale**

The health burden of kidney disease in diabetes mellitus type 2 is substantial and associated with high morbidity and mortality among adults<sup>24</sup>. Management of kidney disease in type 2 DM whether acute, chronic or end stage is highly costly. However, it can be preventable by patient awareness and early treatment of DM 2 by antidiabetic medication, as well as lifestyle modification, such as cessation of cigarette smoking, physical exercise, diet modifications<sup>2</sup>. Not only that but also it will enable

avoidance of fatal outcomes such as ESRD and hyperkalemia which can cause sudden death by interfering with cardiac rhythm ending up with cardiac arrest in asystole. This can be delayed or prevented by lesser expensive interventions such as exercising, dietary changes, cigarette smoking cessation, control of blood pressure and lipid control<sup>11</sup>. Findings from this study shows the distribution of clinico biochemical indicators of kidney disease among newly diagnosed DM type 2 adults, hence emphasizing on the significance of early detection of markers of kidney disease among asymptomatic adult patients who are recently diagnosed with diabetes mellitus type 2. This enables taking appropriate and adequate measures when a patient has been diagnosed with DM 2, including identifying kidney disease at the initial visit and maintaining proper use of antidiabetic medications, life style modification and avoidance of nephrotoxic drugs and foods Example NSAIDS and foods rich in salt respectively<sup>2</sup>, which may cause further damage to the kidney. Henceforth, early detection of kidney disease during diagnosis of DM 2 is impactful on management and control approaches<sup>3,18</sup>. Thus minimizing the number of patients developing ESRD and therefore minimizing clinical effects experienced by patients during this end stage. Not only that but also, it minimizes the cost of treating patients by renal replacement therapy, which is more expensive compared to treatment in initial stage. Moreover, early detection of markers of kidney disease, minimizes the risk of developing ESRD thus reducing the Psychosocial impact which is incurred by the patient and relatives during the time of disease management.

#### **1.4 Research Questions**

- I. What is the distribution pattern of kidney disease among newly diagnosed diabetes mellitus type 2 adults in Dar es Salaam?

- II. What is the magnitude of kidney disease among newly diagnosed diabetes mellitus type 2 adults in Dar es Salaam?
- III. How will the distribution of risk factors (smoking, alcohol consumption, glycemic levels, and obesity) be by levels of albuminuria and estimated glomerular filtration rate among newly diagnosed adults with diabetes mellitus type 2 adults in Dar es Salaam

## **1.5 Objectives**

### **1.5.1 Broad Objective**

To determine the distribution of clinical biochemical indicators of kidney disease among newly diagnosed diabetes mellitus type 2 adults in Dar es Salaam

### **1.5.2 Specific Objectives**

- I. To determine the prevalence of kidney disease among newly diagnosed diabetes mellitus type 2 adults in Dar es Salaam
- II. To determine the distribution of social demographic characteristics (age, gender, marital status, level of education, income status) of adults by kidney disease among newly diagnosed DM 2 patients in Dar es Salaam
- III. To determine the distribution of levels of albuminuria and estimated glomerular filtration rate by age and gender among newly diagnosed DM 2 adult patients in Dar es Salaam.
- IV. To determine the distribution of risk factors (smoking, alcohol consumption, glycemic levels, obesity) by of levels albuminuria and estimated glomerular filtration rate among newly diagnosed adults with DM 2 in Dar es Salaam.

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

The number of individuals with kidney disease in diabetes mellitus is rising globally, mirroring the increasing prevalence of type 2 diabetes mellitus.<sup>18</sup> In 2021, 537 million people worldwide, which accounts for 11% of the global population, had diabetes mellitus, and this number is expected to increase to 783 million people, which will be 12% of the population by 2045. The growing burden of type 2 diabetes mellitus is secondary to the pandemic of obesity, which has mainly been caused by increased intake of processed food, reduced physical activity, and increased sedentary behavior. This lifestyle correlates with the global increase in urbanization and technological development.<sup>18</sup> Kidney disease affects about 20-40% of patients with diabetes mellitus, most of them being DM type 2 patients.<sup>21</sup>

The Australian journal article of 2015 on diabetic kidney disease also reported that improved prognosis, together with an increase in the incidence of DM type 2, has contributed to a rise in kidney disease.<sup>17</sup> Of the approximately 400 million people globally with DM type 2, about half were diagnosed with chronic kidney disease. One in five adults with DM type 2 had an estimated glomerular filtration rate of <60ml/min/1.73m<sup>2</sup>, and between 30%-50% have increased urine albumin excretion.<sup>17</sup> This shows the distribution of the clinico biochemical indicators of kidney disease among Diabetes mellitus, type 2 patients. However, it does not show this distribution among newly diagnosed DM 2 adult patients.

The United Kingdom prospective diabetes study on risk factors for renal dysfunction in DM type 2 of 2006 reported DM type 2 being the leading cause of ESRD in the Western world.<sup>26</sup> Most, although not all, patients with DM type 2 develop renal dysfunction during their lifetime.<sup>26</sup> Nearly one quarter (24.9%) of patients developed microalbuminuria within ten years of diagnosis of DM type 2, but only 0.8% developed ESRD, as assessed by elevated plasma creatinine or indication for renal replacement therapy.<sup>26</sup> Annual transition rates between progressive stages of normoalbuminuria to microalbuminuria to macro albuminuria to ESRD were 2-3% annually.<sup>26</sup> This suggested that individuals did not necessarily progress to worsening renal outcomes despite developing microalbuminuria. Early identification of patients likely to progress to poor renal outcomes allowed the institution to provide appropriate interventions in a timely.<sup>26</sup> Independent risk factors for albuminuria included male sex, increased waist circumference, plasma triglycerides, LDL cholesterol, glycated hemoglobin, increased white blood cells, history of cigarette smoking and previous retinopathy.<sup>26</sup> The mentioned risk factors, contribute to a rise in clinico biochemical indicators of kidney disease, and if not detected early, may cause patients to progress to poor renal outcomes.

A comparative Cross-sectional study done in 2020 in Saudi Arabia on diabetic kidney disease in patients newly diagnosed with DM 2 reported a prevalence of 45.75% of kidney disease among 153 newly diagnosed DM 2 patients.<sup>27</sup> Diabetic kidney disease was diagnosed based on urine albumin to creatinine ratio elevated to greater than 30mg/g in two out of three morning urine samples and estimated glomerular filtration rate of <60ml/min/1.73m<sup>2</sup> using 2009 CKD-EPI collaboration creatinine equation. In this study, the frequency of increased UACR greater than 30, eGFR of less than 60

were, 88.6% and 5.2% respectively. Whereby 54.9% had microalbuminuria, 39.2% had macroalbuminuria, and 5.9% had severely increased albuminuria.<sup>27</sup>

In one Cross-sectional study done in 2021 in Jordan, the prevalence of kidney disease among 1398 patients with type 2 diabetes mellitus of 50.14% was reported. On the other hand, 625 patients (44.7%) had microalbuminuria, and 268(19.17%) had chronic kidney disease with an estimated glomerular filtration rate of <60ml/min/1.73m<sup>2</sup>. Kidney disease in diabetes mellitus was associated with old age >60 years.<sup>6</sup>

A case-control study conducted at a tertiary hospital in Bangladesh reported almost 23% of type 2 diabetic patients had diabetic nephropathy during diagnosis. They mostly had microalbuminuria.<sup>28</sup> The presence of smoking, family history of diabetes and diabetic nephropathy, increased body mass index and increased glycosylated hemoglobin were significant risk factors for diabetic nephropathy among newly diagnosed type 2 diabetic patients.<sup>28</sup>

The prevalence of CKD varies in countries across the world in patients with type 2 diabetes mellitus. These range from 27% to 84% in China and Tanzania respectively.<sup>18</sup> A systematic review in 2015, which included data from more than 30 countries in Europe, North America, Asia, and Australia, showed an annual incidence of albuminuria of about 8% in type 2 diabetes mellitus and a low estimated glomerular filtration rate of <60ml/min/1.73m<sup>2</sup> of about 2–4% in both type 1 and 2 Diabetes mellitus.<sup>29</sup>

A retrospective cohort study done from 2013 to 2017 at Harari Region East Ethiopia on time to acute kidney injury and its predictors among newly diagnosed type 2 diabetic patients in government hospitals, which included 502 participants, reported that 14.5% of the population developed acute kidney injury, with a median survival time of 57 months.<sup>4</sup> Delays in follow-up and physical activities were among the significant predictors of acute kidney injury in newly diagnosed type 2 diabetes mellitus patients in this study.<sup>4</sup>

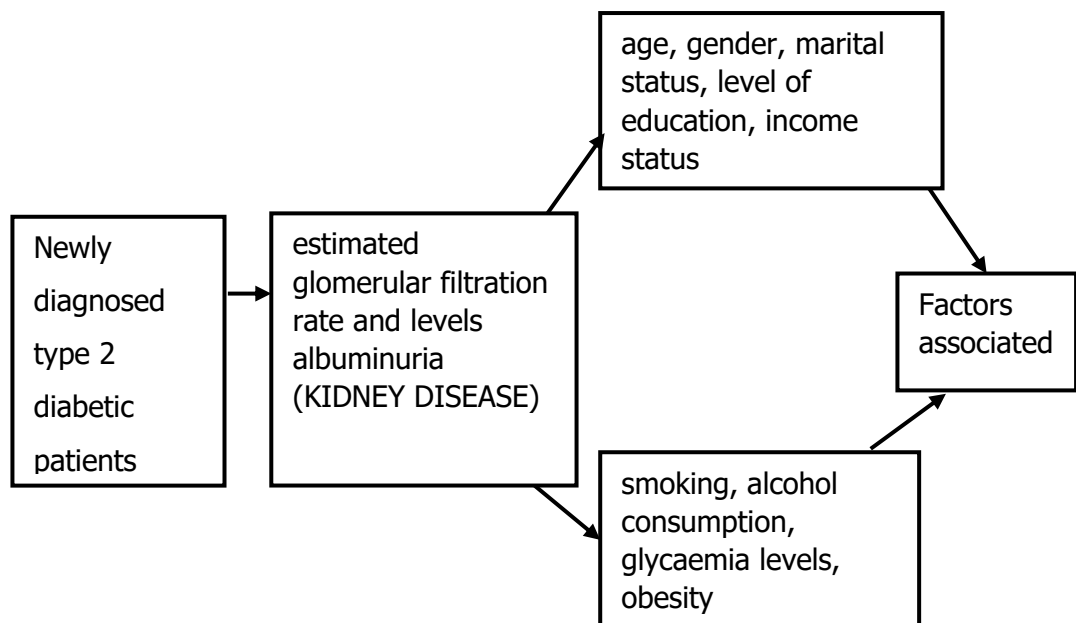
An institutional-based cross-sectional study on CKD and associated risk factors assessment among DM patients was conducted at Gondar University Hospital in Ethiopia in 2016.<sup>30</sup> It involved 229 participants, of which 50.2% of the participants were females, and the mean age was 47 years. The frequency of CKD was 21.8%. Of all participants, 3.9% had renal impairment, while 46% had albuminuria.<sup>30</sup> DM type 2, older age and longer duration of DM were the independent risk factors associated with CKD.

A cross-sectional study done in 2018 at Mulago Hospital in Uganda of microalbuminuria among newly diagnosed diabetic patients reported a prevalence of 47.4%. In this study, male patients had a higher prevalence of microalbuminuria (51.1%) than females (43.5%). Patients with obesity had a higher prevalence of microalbuminuria compared to those without obesity, which was 57.7% and 49.6%, respectively.<sup>31</sup> Thus male gender and obesity were factors associated with increase in one of the clinicobiochemical indicators of kidney disease, "microalbuminuria". In this study, pregnancy was the independent factor associated with microalbuminuria, while

mild and moderate physical activities at work were inversely associated with microalbuminuria, respectively.<sup>31</sup>

Another cross-sectional study on the prevalence of chronic kidney disease in diabetic adult outpatients was conducted at Bugando Hospital diabetic clinic in Mwanza, Tanzania. It included 369 participants. 309(83.7%) participants had CKD, and 295(80.05%) had albuminuria and 91(24.7%) had estimated glomerular filtration rate of  $<60\text{ml}/\text{min}/1.73\text{m}^2$ . Older age was significantly associated with CKD in this population.<sup>32</sup> However this study was not done among newly diagnosed DM type 2 patients, but still showed the distribution of clinical biochemical indicators of kidney disease among DM type 2 patients, and older age, among the significant risk factors.

### Conceptual Framework



## **CHAPTER THREE**

### **3.0. METHODOLOGY**

#### **3.1. Study design**

A cross-sectional descriptive study was conducted among newly diagnosed adult patients with type 2 diabetes mellitus attending Diabetic Clinics in Dar es Salaam.

#### **3.2. Study area**

The study was conducted in the Dar es Salaam region at diabetic clinics in the regional referral hospitals, Amana, Mwananyamala, and Temeke. Dar es Salaam region is located at 6°48'South, 39°17' east on the Eastern coast of East Africa<sup>33</sup>. It comprises five municipalities: Kinondoni, Ilala, Temeke, Ubungo and Kigamboni. According to the current census, the Dar es Salaam region's population in 2022 is 5,383,728<sup>34</sup>. It is an important city for Industrial, business, government activities, and education<sup>34</sup>. Dar es Salaam region has 3 regional referral hospitals(RRHs), including Amana, Mwananyamala, and Temeke. These are located in Ilala, Kinondoni, and Temeke Municipality, respectively. The diabetic clinics in these regional referral hospitals, operate on daily working days and focus on diagnosis, and management of diabetes mellitus patients and related complications they may develop. The patient in these clinics are diagnosed and treated based on the Tanzanian standard treatment guidelines for Diabetes mellitus.

#### **3.3. General population**

All newly diagnosed DM type 2 adult patients in Dar es Salaam

### **3.4. Target population**

All newly diagnosed DM type 2 adult patients who attended diabetic clinics in Dar es Salaam.

### **3.5. Study population**

Randomly selected newly diagnosed adult DM type 2 patients who attended diabetic clinics in Dar es Salaam.

### **3.6 Eligibility criteria**

#### ***3.6.1 Inclusion criteria***

- I. All newly diagnosed type 2 diabetes mellitus adult patients attending diabetic clinics in Dar es Salaam who provided consent to participate in the study.

#### ***3.6.2 Exclusion Criteria***

- I. Patients who could not communicate (were severely ill newly diagnosed DM type 2 patients)
- II. Patients with documented urinary tract infection, since it is associated with proteinuria

### **3.7 Sample size estimation**

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

Where by:

Z—1.96 corresponding to 95% CI

P— 45.75%, Prevalence of kidney disease in newly diagnosed DM 2 adult patient's population, obtained from previous study<sup>27</sup>

ε— margin of error at 95% CI which is 5%.

n—projected sample for this study

$$n = \frac{1.96^2 \cdot 0.4575(1 - 0.4575)}{0.05^2} = 381$$

Therefore, the overall sample size for this study was 381± 10, which was 380 for this study.

### **Justification of formula**

The Kish Leslie formula for single proportion estimation of the sample was used to calculate the internally valid sample size for estimating the prevalence of kidney disease among newly diagnosed DM 2 patients. The proportion used for calculating sample size was obtained from a corresponding study done by M. Aboelnasr et al in Saudi Arabia on kidney disease among patients newly diagnosed with type 2 diabetes mellitus<sup>27</sup>. The study aimed to determine the incidence and association of kidney disease in newly diagnosed type 2 diabetic mellitus patients, where kidney disease was determined by estimated glomerular filtration rate and urinary albumin to creatinine ratio<sup>27</sup>. Thus, using similar proportions ensured the validity of results and minimized bias.

### **3.8 Sampling procedure**

In this study, strata sampling was employed to categorize diabetic clinics in Dar es Salaam. Diabetic clinics were placed in stratas in national, regional, district, health centers, and dispensaries. One cluster of diabetic clinics in regional hospitals was then picked to be used for the study. Finally, study participants (380 participants) were selected using simple random sampling from selected diabetic clinics in regional

referral hospitals. About 127 participants were selected from each diabetic clinics from regional referral hospital for the required sample size.

### **3.9 Study variables**

#### **3.9.1 Dependent variable**

The dependent variable of this study was kidney disease status. A combination of eGFR and UACR assessed kidney disease status.  $<60$  in or  $\geq 60$  mL/min/1.73m<sup>2</sup>, with and without low estimated glomerular filtration rate, respectively, according to 2013 KIDGO definition<sup>3</sup>

#### **3.9.2 Independent variables**

The independent variables of this study were categorized into social demographics and the patient's lifestyle risk history.

- Social demographics: age, gender, occupation, education level
- Lifestyle and risk history: BMI, RBG, history of tobacco, history of alcohol, family history of diabetes mellitus, familial history of kidney disease

### **3.10 Data Collection**

Data collection comprised of sociodemographic, clinical, and laboratory variables. The principal investigator and a trained research assistant (nurse) collected data from study participants, from selected hospitals.

#### **Sociodemographic and clinical variables**

A structured questionnaire was used to collect Social demographic and Clinical variables by the principal investigator and research assistants as done in a previous

study<sup>31</sup>. Sociodemographic data included gender, age, residence, marital status, level of education, employment and income level which was described using the International Socio-Economic Index of occupation Status(ISEI). Where by high income (High ISEI Scores- typically higher skilled, high-income jobs), mid income (mid-range ISEI Scores-jobs requiring moderate skills and education). Low income (Low ISEI Scores-low skilled, low income jobs).

Clinical data included; Family history of diabetes mellitus, familial history of kidney disease with diabetes mellitus type 2, consumption of alcohol, cigarette smoking, and Body mass index.

The principal investigator obtained the study participants' social demographic and clinical information by taking a specific focused history. Information gathered was entered into the questionnaire.

### **Weight and Height**

A research assistant (a trained nurse) measured a participant's body weight by using a weighing scale (Seca, China, 2017) to the nearest 0.5 kg. Body weight was measured without shoes. Participants stood with feet close together, arms at the side and reading was taken. Height was measured using a height measuring rod (Seca, China, 2017). The participant was asked to stand on the floor without shoes, parallel to the height measuring rod, and was asked to look directly forward while standing. Height was measured and recorded to the nearest 0.5cm.

### **Body mass index**

Body Mass Index was calculated using a person's height and weight, using the formula:

BMI = weight in kg/Height in m<sup>2</sup>.

The BMI parameters used per 2023 WHO guideline<sup>35</sup> were be as shown in the table;

**Table shows Body Mass Index parameters.**

<b>WEIGHT STATUS</b>	<b>BODY MASS INDEX (BMI) Kg/ m<sup>2</sup></b>
Underweight	<18.5
Normal weight	18.5-24.9
Overweight	25.0-29.9
obese	≥30

### **Laboratory variables**

Random blood glucose measurement was done by the principal investigator and the research assistant using a glucometer; (Gluco plus Inc., Canada 2004). The distal site on the middle finger was wiped with an alcohol swab and a finger prick was done using a lancet, the initial blood drop was wiped, the second blood drop was placed on the test strip and the reading was obtained in mmol/L. Values above 11.1mmol/L were considered as hyperglycemia.

The Serum Creatinine (Scr) test was done by a research assistant (trained laboratory technician) using (the Mindray BS -240 clinical chemistry analyzer Laboratory machine, China 2019). A venous blood sample was taken from study participants, and at least 2.5mls of blood was drawn by a 5CC syringe by a trained nurse and principal investigator. Samples were refrigerated (2<sup>0</sup>C) to 8<sup>0</sup>C) in the laboratory for serum creatinine measurement within 8 hours. Samples were analyzed as soon as they reached the Laboratory. Serum creatinine was measured and reported by the laboratory technician. The estimated glomerular filtration rate was calculated using

the reported serum creatinine concentration and validated Modification of diet in renal disease (MDRD) formula<sup>36</sup>

$$eGFR \text{ (mL/min/1.73 m}^2\text{)} = 175 \times (\text{Scr}/88.4)^{-1.154} \times \text{age}^{-0.203} \times g \times e,$$

whereby.

Scr is serum creatinine in  $\mu\text{mol/L}$ ,

g is a gender factor (male = 1, female = 0.742)

e is an ethnicity factor (African American = 1.212, other ethnic groups = 1).

The estimated glomerular filtration rate was categorized as.

<60 in or  $\geq 60\text{mL/min/1.73m}^2$ , with and without low estimated glomerular filtration rate respectively according to 2013 KIDGO definition,2013<sup>3</sup>.

The procedure for collecting urine was explained to the study participants by the principal investigator. Each participant was given a urine container and instructed to provide a sample of midstream urine measuring 10mls. A spot urine sample collected in the container was transported to the laboratory in less than 8 hours and used for measurement of urine albumin to creatinine ratio (ACR) using a chemistry analyzer (Mindray BS-240, China 2019) laboratory machine, by the laboratory technician. ACR of <30mg/g meant the participant had normal urine albumin; an ACR of 30-299mg/g meant microalbuminuria; an ACR of >300mg/g meant macro albuminuria<sup>31</sup>.

Participants with an estimated glomerular filtration rate of <60mL/min/1.73m<sup>2</sup> and urine ACR > 30mg/g were considered to have kidney disease<sup>27</sup>.

### **3.11 Data analysis**

The data analysis used SPSS version 28.0 (IBM SPSS Statistics for Windows Version 28.0. Armonk, NY: IBM Corp). Data was entered into SPSS then cleaned for forgotten, missing, and double entries. Different continuous variables were recorded into a category, while some categorical data were recorded due to the distribution of data within a level of variables.

Age, BMI, RBG, Serum creatinine level, eGFR, and UACR were summarized using mean and standard deviation. After being summarised, these variables were transformed into a category.

Age was categorized into  $\leq 40$ , 41-59, and 60+, BMI:  $< 25$ , 25-29.9 and 30+. This categorization was based on the data distribution and commonly used grouping in the literature studies.

A standard categorization was assumed for ACR and eGFR. ACR was categorized into  $< 30\text{mg/g}$ , 30-299mg/g, and  $> 300\text{mg/g}$  for normal urine albumin, microalbuminuria, and macro albuminuria, respectively. eGFR was categorized into  $< 60$  in or  $\geq 60\text{mL/min/1.73m}^2$ , with and without 4t low estimated glomerular filtration rate, respectively.

The participants with an estimated glomerular filtration rate of  $< 60\text{mL/min/1.73m}^2$ , and urine ACR  $> 30\text{mg/g}$  were considered to have kidney disease.

All categorical data, such as Gender, level of education, family history of diabetes mellitus, familial history of kidney disease with diabetes, intake of alcohol, cigarette smoking, and continuous variables that were transformed into categorical variables, were summarized using absolute counts and percentages.

The data were presented using text, tables, and figures, depending on the volume of information aggregates required to be presented together to the objectives of this study.

Proportional comparisons of the predictor variables with kidney disease status were done using the chi-squared test. The predictor variables that achieved a significance level of 0.2 in the chi-square test were collectively analysed in a multivariable logistic regression, and the results were expressed as adjusted odds ratio (aOR) with a corresponding 95% confidence interval (CI). A p-value less than 0.05 was considered statistically significantly associated with kidney disease.

### **3.12 Dissemination of Results**

The research result findings will be disseminated to the HKMU Library, the Ministry of Health, the Diabetes Society of Tanzania and the association of Physicians of Tanzania through research reports, scientific conferences, and publications.

## **CHAPTER FOUR**

### **4.0 Ethical consideration**

Ethical clearance was sought from the HKMU Institutional Research and Ethics Committee. Permission to conduct the study was issued by the Dar es Salaam Regional Administrative Secretary, Ministry of Health, and the medical officer in charge of the RRHs.

Before data collection, this study's purpose, objectives, and procedures were explained to the study participants. The participants were explained about the slight pain during the withdrawal of the sample and were assured that the pain would resolve immediately after the procedure. Voluntary informed consent forms were given to all participants to read and sign. For some participants who could not read and write, the consent forms were read to them, and a thumbprint was used as a signature alternative. No personal identification was used in the data collection form. All personal identification was given a serial number corresponding to the participant's identifications that were known to the principal investigator. The data access was controlled by principal investigators only. The participants were informed about their right to withdraw from the study at any time without affecting their services in particular study settings. The principal investigator was responsible for all questions and concerns from participants. Newly diagnosed DM type 2 adult patients who were found to have clinico biochemical indicators of kidney disease were informed and referred for further management.

## CHAPTER FIVE

### 5.0 Results

#### 5.1 The social demographics and baseline information of the study participants

This study was conducted for 10 months from November 2023 to August 2024, and 380 newly diagnosed DM type 2 patients in regional referral hospitals in Dar es Salaam were recruited.

Table 1, characterizes the distribution of participants across social demographics and participant's history. The mean age was  $57.2 \pm 13.0$  standard deviation. The minimum age was 28, and the maximum was 84. The study participants were relatively evenly distributed across gender groups, with the majority aged sixty and above. The majority of the study participants 85.8%, were married. Regarding education, the distribution was relatively equal between primary, secondary, and college education, with only 10.5% having higher education. A significant portion of the participants (40.3%), were self-employed. The majority (56.3%), had a medium income.

Almost three-quarters of the study participants had a history of alcohol use, while only 3.7% had a history of smoking. Of the 232(61.1%) study participants who had a history of alcohol consumption, 135(58.2%) had drunk for over ten years. Also, of these 232(61.1%), 120(51.7%), 109(47.0%) and 3(1.3%) drunk weekly, occasionally and daily respectively. The median number of cigarette packets smoked was two, with the minimum being one and the maximum being five. Seven (50%) of the total smokers smoked two packets per day.

One-fifth of the participants had a family history of diabetes. The mean BMI was 25.0  $\pm$  4.6 standard deviation. The minimum BMI was 18, and the Maximum BMI was 45. Most participants fell within the BMI range of 18.5-24.9, and nearly half, 45.5%, were hyperglycaemic. The mean RBG was 11.2 and the standard deviation was 4.2.

**Table 1: Frequency distribution table of Social demographic characteristics of Newly diagnosed adults with DM 2 in Dar es Salaam. (N=380)**

Variables	Frequency(%)
Gender	
Male	177(46.6)
Female	203(53.4)
Age	
<40	45(11.8)
41-59	166(43.7)
60+	169(44.5)
Marital status	
Married	326(85.8)
Widowed	45(11.8)
Divorced	5(1.3)
Single	4(1.1)
Education level	
Primary	120(31.6)
Secondary	115(30.3)
College	105(27.6)
Higher Education	40(10.5)
Employment status	
Unemployed	117(30.8)
Self employed	153(40.3)
Employed	110(28.9)
Income level	
Low	160(42.1)
Mid	214(56.3)
High	6(1.6)
History of alcohol consumption	
No	148(38.9)
Yes	232(61.1)
History of tobacco cigarette smoking	
No	366(96.3)
Yes	14(3.7)
Family History of DM 2	
No	82(21.6)
Yes	298(78.4)
BMI	
<18.5	6(1.6)
18.5-24.9	195(51.3)
25-29.9	121(31.8)
30+	58(15.3)
Hyperglycemia	
No	207(54.5)
Yes	173(45.5)

## **5.2 The prevalence of kidney disease among newly diagnosed diabetes mellitus type 2 adults in Dar es Salaam**

The average Serum creatinine level was  $90.6 \pm 35.5 \mu\text{mol/L}$  standard deviation, with a minimum of  $39 \mu\text{mol/L}$  and a maximum of  $433 \mu\text{mol/L}$ . The average eGFR was  $71.6 \pm 23.4$  standard deviation, with a minimum of 9 and a maximum of 185. The median UACR was 14.0, with a range of 151 (Minimum = 3 and Maximum = 154).

Among 380 study participants, 110(28.9%), had an eGFR of less than 60. About 85 participants (22.4%) had a UACR greater than 30. About 83 participants (21.8%), had both UACR of greater than 30 and eGFR of less than 60.

## **5.3 The distribution of social demographic characteristics (age, gender, marital status, level of education, income status) of adults by kidney disease among newly diagnosed DM type 2 patients in Dar es Salaam.**

Table 2 shows the distribution of social demographic characteristics according to KD diagnosis status. The KD diagnosis increased with age, where most diagnoses were observed among participants older than 61 years, although it was not statistically significant at  $p < 0.05$ . Kidney disease was more common among females than males, and the association was statistically significant with  $p < 0.001$ . Although the association was not statistically significant, the proportion of KD was most common among divorced and widow marital groups.

**Table 2: Distribution of social demographic characteristics of adults by KD among newly diagnosed DM 2 patients in Dar es Salaam. (N=380)**

Variables	Yes N(%)	No N(%)	X <sup>2</sup> , p-value
Age group			
<40	8(17.8)	37(82.2)	
41-59	30(18.1)	136(81.9)	
60+	45(26.6)	124(73.4)	4.084, .130
Gender			
Male	22(12.4)	155(87.6)	
Female	61(30.0)	142(70.0)	17.196, .000
Employment Status			
Unemployed	32(27.4)	85(72.6)	
Self-employed	30(19.6)	123(80.4)	
Employed	21(19.1)	89(80.9)	3.015, .222
Income level			
Low	35(21.9)	125(78.1)	
Mid	48(22.4)	166(77.6)	
High	0(,0)	6(100.0)	1.720, .423
Education level			
Primary	31(25.8)	89(74.2)	
Secondary	22(19.1)	93(80.9)	
College	24(22.9)	81(77.1)	
Higher Education	6(15.0)	34(85.0)	2.775, .428
Marital status			
Married	66(20.2)	260(79.8)	
Widowed	14(31.1)	31(68.9)	
Divorced	2(40.0)	3(60.0)	
Single	1(25.0)	3(75.0)	3.741, .291

**5.4 The distribution of factors (smoking, alcohol consumption, glycemic levels, obesity) of adults by kidney disease among newly diagnosed DM type 2 patients in Dar es Salaam.**

Table 3, shows the distribution of KD according to the participant’s lifestyle history. The occurrence of KD increased with BMI, with the majority being 25-29.9 and 30+, with relatively equal proportions of 31(25.6%) and 14(24.1%), respectively. The distribution of Kidney disease was relatively equal between those who were

hyperglycemic and those who were not. The distribution was typical among those who had a history of alcohol consumption and cigarette smoking, with proportions of 55(23.7%) and 4(28.6%), respectively.

**Table 3: Distribution of characteristics of adults by KD among newly diagnosed DM 2 patients in Dar es Salaam. (N=380)**

Variables	Yes N(%)	No N(%)	X <sup>2</sup> , p-value
BMI Group			
<25	38(18.9)	163(81.1)	
25-29.9	31(25.6)	90(74.4)	
30+	14(24.1)	44(75.9)	2.206, .332
Hyperglycemia			
No	44(21.3)	163(78.7)	
Yes	39(22.5)	134(77.5)	.091, .762
Family history of DM2			
No	18(22.0)	64(78.0)	
Yes	65(21.8)	233(78.2)	.001, .978
Family history of KD			
No	82(21.9)	292(78.1)	
Yes	1(16.7)	5(83.3)	.096, .757
History of alcohol consumption			
No	28(18.9)	120(81.1)	
Yes	55(23.7)	177(76.3)	1.213, .271
History of cigarette smoking			
No	79(21.6)	287(78.4)	
Yes	4(28.6)	10(71.4)	.386, .535

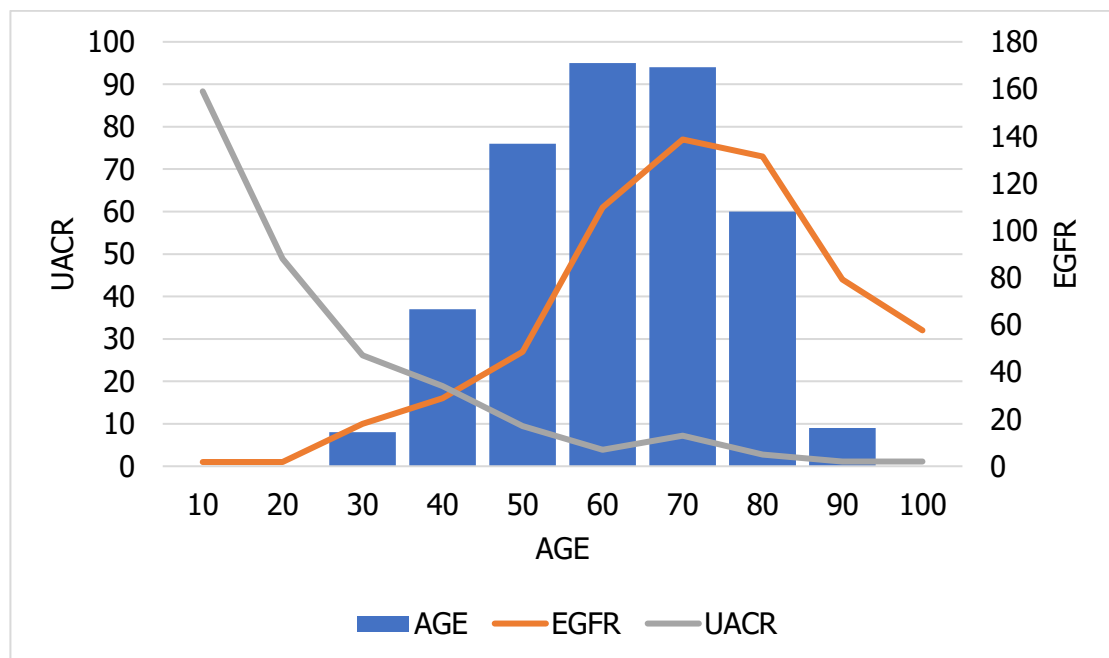
### **Factors associated with KD among newly diagnosed DM type 2**

Age and gender were found to have a p-value <0.2. Table 4, the multivariable logistic regression was run with age and gender as factors for the prevalence of KD. Being female with DM type 2 is associated with a decreased chance of kidney disease (p<0.05).

**Table 4: The multivariate logistic regression of age and gender diagnosed with kidney disease among newly diagnosed DM type 2 patients in Dar es Salaam. (N=380)**

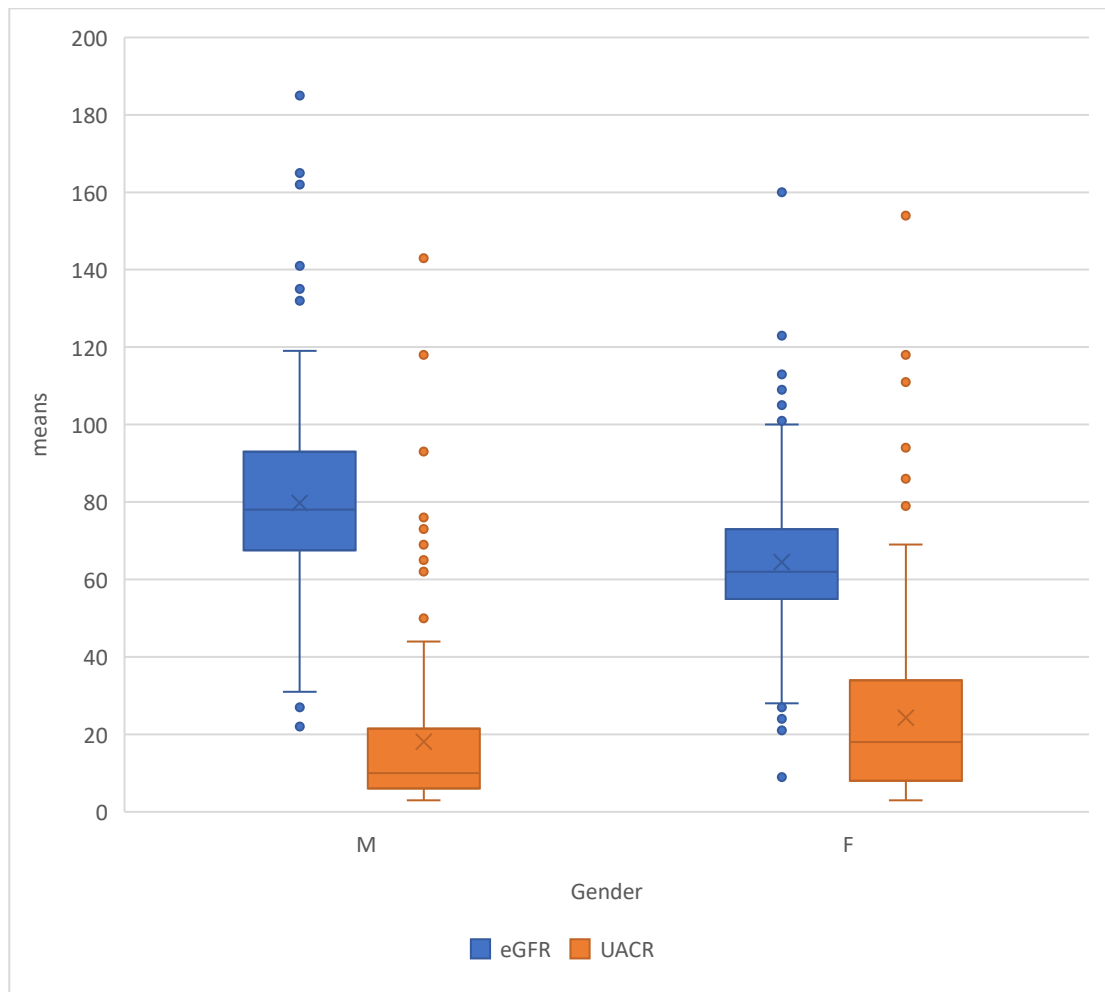
Variables	Yes N(%)	No N(%)	AOR for 95% C.I (Lower-Upper)	P value
Age group				
<40	8(17.8)	37(82.2)		
41-59	30(18.1)	136(81.9)	.847(.352-2.037)	.711
60+	45(26.6)	124(73.4)	.517(.220-1.216)	.131
Gender				
Male	22(12.4)	155(87.6)		
Female	61(30.0)	142(70.0)	.323(.188-.556)	.000

**Figure 1 shows the distribution of age, eGFR, and UACR.**



**Figure 1: The distribution of levels of albuminuria and estimated glomerular filtration rate by age among newly diagnosed DM 2 adult patients in Dar es Salaam.**

**Figure 2: The distribution of levels of albuminuria and estimated glomerular filtration rate by gender among newly diagnosed DM 2 adult patients in Dar es Salaam**



**Figure 3: The distribution of levels of albuminuria and estimated glomerular filtration rate by gender among newly diagnosed DM 2 adult patients in Dar es Salaam.**

## CHAPTER SIX

### 6.0 DISCUSSION

This study determined the clinico biochemical indicators of kidney disease among newly diagnosed DM 2 patients attending diabetic clinics in Dar es Salaam. Among the study participants, 28.9%, had an eGFR of less than 60. About 22.4% had a UACR of greater than 30. 21.8%, had both UACR of greater than 30 and eGFR of less than 60. These findings contrast with the study done in Saud Arabia whereby there was a higher frequency of UACR greater than 30 than that of decreased estimated glomerular filtration rate<sup>27</sup>. The frequency of increased UACR greater than 30 and eGFR less than 60 were, 88.6% and 5.2% respectively<sup>27</sup>. The Discrepancy in results may be explained by the difference in the much larger sample size used in the current study, the difference in geographical location, different methodology in the formula used to calculate eGFR and criteria for recruiting newly diagnosed DM 2 patients. The study as mentioned above included patients diagnosed with DM 2 within six months.

In contrast, in the current study, patients recruited were those who had just been recently diagnosed with diabetes mellitus type 2 and had not started on antidiabetic medications. This can be explained by the compromise of the integrity of the glomerular filtration barrier that results from long-standing hyperglycemia, leading to increased albumin filtration into the urine<sup>2</sup> Higher frequency of eGFR of less than 60(28.9%) than the frequency of UACR of greater than 30 (22.4%) portrays increased chances of nephritis than nephrosis among newly diagnosed DM 2 adults. There should be consideration of the use of renal protective pharmacotherapy to target nephritis during the initiation of antidiabetic drugs for a newly diagnosed DM type 2 patient with clinical biochemical indicators of kidney disease.

In this study, kidney disease increased with age. Kidney disease was mostly observed among participants older than 60 years. These findings corresponded with other cross-sectional studies in Jordan and Ethiopia, whereby kidney disease in patients with DM 2 increased with older age >60 years<sup>6,30</sup>. The estimated glomerular filtration rate increased with age above 18 years up to 60 years and decreased with age above 60. The increase of eGFR among adults aged less than 60 years may be explained by an increase in metabolic and protein turnover rate, while the decrease of eGFR among newly diagnosed DM 2 patients aged 60 years and above may be explained by significant physiological process of aging causing nephron loss as well as functional and structural changes in the kidneys. The pathological hyperglycemia in the glomerular filtration barrier worsens the glomerular filtration rate, increasing kidney disease with age above 60 years<sup>2,6,24</sup>. Moreover, UACR decreased with age, among newly diagnosed DM 2 adults aged less than 60 years, and increased among patients aged greater than 60 years. This may be explained by the increased permeability of albumin in the injured glomerular basement membrane and the reduction in muscle mass in adults above 60 years of age, hence a decrease in urinary creatine clearance, which increases UACR<sup>2</sup>.

In this study, kidney disease was common among females (30%) compared to males (12.4%). However multivariable regression showed that being female was associated with lower risk of kidney disease. The association was statistically significant with  $p < 0.05$ . This was contrary to the study in Uganda, where males had a higher prevalence of microalbuminuria than females. 51.1% and 43.5% respectively<sup>31</sup>. This difference may be explained by the fact that the study mentioned above used a single clinico-biochemical indicator (albuminuria) of kidney disease. In contrast, this study

used albuminuria and eGFR as clinico-biochemical indicators of kidney disease. This study focused on newly diagnosed DM 2 adults, while the study as mentioned earlier comprised of both DM 1 and 2 newly diagnosed patients. The lower correction factor value in the MDRD equation for calculating the eGFR for females, explains the decreased risk of kidney disease in females. Moreover, the difference in females' and males' glomerular structure, glomerular hemodynamics, and metabolism of hormones have a great role in the gender differences in kidney disease<sup>36,37</sup>.

Proportion of KD was most common among divorced (40%) and widowed (31%) marital groups, compared to being single (25%) and married (20.2%) among newly diagnosed DM 2. However, these findings were not statistically significant. Moreover, Level of education as well as employment status, had no statistical significance on clinico-biochemical indicators of kidney disease among newly diagnosed DM 2 adult patients.

Kidney disease increased with BMI, with the majority being 25-29.9 and 30+, with relatively equal proportions of 31(25.6%) and 14(24.1%), respectively. This is in line with a study done in Bangladesh where increased BMI was a significant risk factor for diabetic nephropathy among newly diagnosed DM 2 patients<sup>28</sup>. It also corresponds with a study in Uganda, whereby Patients with obesity had a higher prevalence of microalbuminuria compared to those without obesity, which was 57.7% and 49.6%, respectively.<sup>31</sup> This can be explained by the compensatory hyperfiltration that occurs in individuals with increased BMI to meet metabolic demands, thus increasing intraglomerular pressure which destroys the glomerular basement membrane and increases the risk of developing kidney disease<sup>2</sup>.

Kidney disease frequency was relatively higher among individuals with hyperglycemia, compared to those without hyperglycemia, 22.5% and 21.3% respectively. The glycemetic factor was not statistically significant in this study. This is contrary to the study done in Bangladesh, which reported hyperglycemia as a substantial risk factor for developing kidney disease among DM 2 patients<sup>28</sup>. This discrepancy may be explained by the use of glycated hemoglobin in the assessment of glycemetic levels in the study above, compared to the use of a single reading of random blood glucose among newly diagnosed DM 2 adults, in this study. Persistent hyperglycemia causes excessive formation of extracellular matrix and glomerular mesangial dilation. Thus it gradually destroys the glomerular capillaries and affects glomerular filtration resulting in kidney disease<sup>2,21,28,38</sup>.

Kidney disease distribution was typical among those who had a history of alcohol consumption and cigarette smoking, with proportions of 55(23.7) and 4(28.6), respectively, despite not being statistically significant. This finding corresponds with the UK prospective diabetes study report on risk factors of renal dysfunction in DM 2, which includes cigarette smoking among risk factors for increased albuminuria in DM 2 patients. This is explained by the presence of nicotine in cigarettes which has a toxic effect on podocytes, that causes damage to the glomerular basement membrane hence resulting in kidney disease. Also, alcohol consumption affects the filtration ability of the glomerular basement membrane and hence may result in kidney disease.

## **CHAPTER SEVEN**

### **7.0 STUDY STRENGTH LIMITATIONS AND MITIGATIONS**

Strength includes, the study followed appropriate standards of study design. From calculation of sample size, sampling procedure, recruitment of study participants, data collection and analysis of data. Not only that but also appropriate statistical tests were used in the data analysis in this study.

There were some limitations to be addressed in this study. Firstly, the urine samples used to calculate the urine albumin to creatinine ratio were obtained from the study participants' random spot urine void, rather than a first-morning void after the individual awakes from sleep. The morning void is preferred since it increases sensitivity and excludes the relatively benign condition of orthostatic proteinuria, which ceases during the day while an individual sleeps supine.<sup>39</sup> The multivariate logistic regressions used to calculate the Adjusted odds ratio for the respective variables were done to mitigate this limitation.

Another limitation is using a single random blood glucose test to determine glycemic levels. The use of glycosylated hemoglobin which gives an average of 2-3 months of blood sugar in hemoglobin would give more reliable glycemic levels for kidney disease, among newly diagnosed DM type 2 adult patients. Glycosylated hemoglobin was not used in this study to determine glycemic levels due to financial constraints

## CHAPTER EIGHT

### 8.0 Conclusion

Clinico-biochemical indicators of kidney disease among newly diagnosed DM 2 adult patients included reduced estimated glomerular filtration rate to  $<60\text{mL}/\text{min}/1.73\text{m}^2$  and increased UACR  $> 30\text{mg}/\text{g}$ . This study had more participants with reduced estimated glomerular filtration rate  $<60\text{mL}/\text{min}/1.73\text{m}^2$  than those with increased UACR  $> 30\text{mg}/\text{g}$ . Moreover, the study findings show that, despite females having a higher proportion of clinical-biochemical indicators of kidney disease, they have a lower risk of developing kidney disease.

### 8.0 Recommendation

It is recommended to emphasize early screening of clinico-biochemical indicators during the diagnosis of diabetes mellitus type 2 in adult patients. This includes screening serum creatinine to obtain an estimated glomerular filtration rate and for albuminuria, since some of recently diagnosed patients with DM2 are already having features suggestive of KD, therefore, kidney functional screening immediately after DM type 2 diagnosis should be emphasized for early detection and appropriate management of KD among this population. Also regular monitoring of these clinico biochemical indicators in short intervals during follow-up of the DM 2 patients attending diabetic clinics. Further studies are to be conducted on appropriate renal protective pharmacotherapy to be administered to newly diagnosed DM 2 adults with clinico- biochemical indicators of kidney disease during the initiation of antidiabetic drugs.

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## APPENDICES

### APPENDIX I: QUESTIONNAIRE (ENGLISH VERSION)

#### CLINICO-BIOCHEMICAL INDICATORS OF KIDNEY DISEASE AMONG NEWLY DIAGNOSED ADULTS WITH TYPE 2 DIABETES MELLITUS IN DAR ES SALAAM

1. Date of data collection \_\_\_\_\_
2. Study site. \_\_\_\_\_
3. Residence area. \_\_\_\_\_

#### A. SOCIAL-DEMOGRAPHIC DATA

4. Age (Years) \_\_\_\_\_
5. Gender \_\_\_\_\_ Male  Female
6. Occupation Employed  Unemployed  self-Employment
7. Income level Low  Middle  High income
8. Level of Education Un educated  Informal  Formal Education   
a) Primary Education  b) Secondary education  c) College  d) University
9. Marital status Married  not married  widowed  Divorced
10. Family history of DM 2 Yes  No
11. Family history of kidney disease with DM 2 Yes  No
12. History of alcohol consumption Yes  No 
  - a. If Yes for how long? less than 10 years  or more than 10 years
  - b. how often? Daily  weekly  or occasionally

13. History of Cigarette smoking Yes  No

If YES, How much? \_\_\_\_\_

**B. PHYSICAL EXAMINATION**

**ANTHROPOMETRIC MEASUREMENTS**

14. Height .....cm

15. Weight .....kg

16. BMI..... Kg/M<sup>2</sup>

**BLOOD SUGAR MEASUREMENTS**

17. Random blood Sugar reading ..... mmol/L

**BIOCHEMISTRY**

18. Serum Creatinine .....  $\mu\text{mol/L}$

19. Estimated glomerular filtration rate .....  
mL/min/1.73m<sup>2</sup>

20. Urine Albumin Creatinine Ratio (ACR)..... Mg/g

**APPENDEX II: DODOSO (KISWAHILI)**

**VIASHIRIA VYA KIBAYOKEMIA VYA KIAFYA VYA MAGONJWA YA FIGO KWA  
WAGONJWA WATU WAZIMA WALIOGUNDULIWA NA KISUKARI AINA YA  
PILI DAR ES SALAAM.**

1. Tarehe ya kukusanya taarifa \_\_\_\_\_
2. Eneo la utafiti. \_\_\_\_\_
3. Eneo analoishi. \_\_\_\_\_

**A. TAARIFA ZA WATU ZA KIJAMII**

4. Umri (Miaka) \_\_\_\_\_
5. Jinsia \_\_\_\_\_ Mme  Mke
6. Ajira Ameajiriwa  hajaajiriwa  Amejajiri
7. Kipato Hana Kipato  Kipato kidogo  kipato cha kati  kipato  
kikubwa
8. Kiwango cha elimu Hana Elimu  Elimu isiyo rasmi  Elimu  
rasmi
- a) Elimu ya msingi  b) Elimu ya sekondari  c) Chuo  d) Chuo  
kikuu
9. Ndoa Ana ndoa  Hana ndoa  Mwenza amefariki   
Wameachana
10. Historia ya aina ya pili ya kisukari kwenye familia Ndiyo  Hapana

11. Historia ya magonjwa ya figo kwa wagonjwa wa aina ya pili ya kisukari kwenye familia

Ndiyo  Hapana

12. Historia ya unywaji wa pombe Ndiyo  Hapana

a. Kama ndio kwa muda gani? Chini ya miaka 10  Zaidi ya miaka 10

b. Mara ngapi? Kila siku  Kila wiki  Mara moja

14. Historia ya uvutaji wa sigara Ndiyo  Hapana

Kama ndio, Kiasi gani? \_\_\_\_\_

## **B. UCHUNGUZI WA KIMWILI**

### **VIPIMO VYA ANTHROPOMETRIKI**

15. Urefu .....cm

16. Uzito .....kg

17. Uwiano wa urefu kwa uzito..... Kg/M<sup>2</sup>

### **KIPIMO CHA SUKARI**

18. Kipimo cha sukari kwenye damu..... mmol/L

### **BIOKEMIA**

19. Kipimo cha damu cha kretini .....  $\mu\text{mol/L}$

20. Kipimo cha kuangalia ufanyaji kazi wa figo .....  
mL/min/1.73m<sup>2</sup>
21. Kipimo cha mkojo cha uwiano wa albumin na kretini .....  
Mg/g

### **APPENDIX III: CONSENT FORM (ENGLISH VERSION)**

#### **Title: CLINICOBIOCHEMICAL INDICATORS OF KIDNEY DISEASE AMONG NEWLY DIAGNOSED ADULTS WITH DIABETES MELLITUS TYPE 2 IN DAR ES SALAAM**

I Dr. Consolata D. Kakoko, a resident in the department of Internal medicine, would like to conduct the named study above as necessary requirements for fulfilment of my post graduate studies.

Your participation is required in order to acquire necessary information regarding your health to be used as data in this study. The study aims at determining markers of kidney disease among newly diagnosed adults with diabetes mellitus type 2 in Dar es salaam.

Findings from this study shall be helpful in recommendation of early screening of kidney disease among newly diagnosed adults, with type 2 diabetes mellitus thus early intervention prior to development of further complications. Those adults newly diagnosed adults with type 2 diabetes mellitus, who will meet the inclusion criteria will be recruited into the study and will be interviewed using a questionnaire, which will include their social demographic characteristics and physical examination.

Blood tests for random blood sugar and serum creatinine will be taken. urine will be tested for albumin creatinine ration (UACR). Weight and height will also be measured. There will be a slight pain on veno puncture for blood sample collection.

Study findings will not be released to any unauthorized person.

The participant will not be asked any fee/money and will be free to withdraw at any time during the study.

People to contact in case of questions or problems.

Prof Y. Mgonda, chairperson of department of Internal Medicine

Director of Post Graduate Studies and Research Institute of HKMU

I.....have read/been told of the contents of this form and understood its meaning. Hence, I agree to participate in this study.

Signature ..... (Participant), Date.....

Signature..... (Researcher), Date.....

#### **APPENDIX IV: FOMU YA IDHINI (SWAHILI VERSION)**

#### **VIASHIRIA KIBAYOKEMIA VYA KIAFYA VYA MAGONJWA YA FIGO KWA WAGONJWA WATU WAZIMA KATIKA HATUA YA AWALI YA KUGUNDULIKA NA KISUKARI AINA YA PILI DAR ES SALAAM.**

Jina langu ni Dr. Consolata D. Kakoko, mwanafunzi wa shahada ya uzamili ya magonjwa ya ndani katika chuo kikuu cha kumbukumbu ya Hubert Kairuki. Ninafanya utafiti kuhusiana na viashiria vya magonjwa ya figo kwa wagonjwa watu wazima katika hatua ya awali ya kugundulika na kisukari aina ya pili Dar es salaam kama ilivyoainishwa hapo mwanzo. Utafiti huu ni kati ya vigezo muhimu vinavyohitajika ili niweze kukamilisha masomo yangu ya shahada ya uzamili.

Ushiriki wako ni wa muhimu, ili kuweza kupata taarifa zako za kiafya, zinazohitajika katika utafiti huu. Kulingana na malengo ya utafiti huu ya kutambua viashiria vya magonjwa ya figo kati ya wagonjwa watu wazima, ambao wamegundulika punde na aina ya pili ya kisukari. Utafiti huu utasaidia kutoa mapendekezo ya upimaji wa kina wa magonjwa ya figo katika hatua za awali za kugundulika na kisukari aina ya pili, hivyo kupata matibabu sahihi mapema ili kuepuka matatizo makubwa zaidi ya kiafya yanayotokana na kucheleweshwa kwa kugundulika kwa ugonjwa na kupata tiba sahihi. Wagonjwa watu wazima, walio katika hatua za awali za kugundulika na kisukari aina ya pili, waliotimiza vigezo vya kuhusika wataingizwa kushiriki katika utafiti huu. Watahojiwa kwa maswali maalumu yaliyo katika dodoso ambayo yatahusisha taarifa za kiafya za kijamii, na vipimo vya mwili.

Sampuli ya damu kwa ajili ya vipimo vya sukari na kretini itachukuliwa. Pamoja na sampuli ya mkojo itachukuliwa kwa ajili ya kipimo cha uwiano wa albumini na kretini. Uzito na urefu pia utapimwa.

Kutakua na maumivu ya kuchoma sindano wakati wa kuchukua sampuli ya damu.

Matokeo ya utafiti huu hayatatolewa kwa mtu yeyote asiyehusika.

Mshiriki atakuwa huru kujitoa kwenye utafiti muda wowote na hatatozwa gharama yoyote

Watu wataruhusiwa kuuliza maswali yoyote kama yapo.

Wahusika wa kuwataarifu kama kuna changamoto itayojitokeza ni, Profesa Y. Mgonda mwenyekiti wa idara ya magonjwa ya ndani au mkurugenzi wa mafunzo ya shahada ya uzamili na utafiti wa chuo kikuu cha kumbukumbu ya Hubert Kairuki.

Mimi..... nimesoma/nimesomewa na kuelewa maelezo yaliyotolewa katika fomu hii hivyo nipo tayari kushiriki katika utafiti huu.

Sahihi ya mshiriki..... Tarehe.....

Sahihi ya Mtafiti Mkuu..... Tarehe.....

## APPENDIX V: WHO Diabetes Aetio-pathology Classification<sup>1</sup>.

Type of Diabetes	Description
<b>Type 1 diabetes</b>	β-cell destruction commonly immune mediated, with complete insulin deficiency.
<b>Type 2 diabetes</b>	β-cell dysfunction and insulin resistance, mostly associated with overweight and obesity
<b>Hybrid forms of diabetes</b>	
<ul style="list-style-type: none"> <li>Slowly evolving immune mediated diabetes of adults</li> </ul>	Similar to slowly evolving type 1 in adults, commonly with features of metabolic syndrome
<ul style="list-style-type: none"> <li>Ketosis prone type 2 diabetes</li> </ul>	Presents with ketosis and insulin deficiency.
<b>Other specific types</b>	
<ul style="list-style-type: none"> <li>Monogenic defects of β-cell function</li> </ul>	Result of specific gene mutation
<ul style="list-style-type: none"> <li>Monogenic defects in insulin action</li> </ul>	Caused by specific gene mutations, with features of severe insulin resistance without obesity. Happens with β-cells not compensating for insulin resistance
<ul style="list-style-type: none"> <li>Diseases of exocrine pancreas</li> </ul>	A number of conditions affecting the pancreas, resulting in hyperglycemia (trauma, tumor, inflammation)
<ul style="list-style-type: none"> <li>Endocrine disorders</li> </ul>	Disease with excess secretion of hormones that are insulin antagonists (acromegaly, Cushing syndrome)
<ul style="list-style-type: none"> <li>Drug or chemical induced</li> </ul>	β-cells destruction by medicines or chemicals, which impairs insulin secretion or actions (Glucocorticoids, phenytoin)
<ul style="list-style-type: none"> <li>Infection-related diabetes</li> </ul>	β-cell destruction associated with direct infectious causes (Rubella, cytomegalovirus)
<ul style="list-style-type: none"> <li>Uncommon specific forms of immune mediated diabetes</li> </ul>	Associated with rare immune mediated disease. (Stiff person syndrome, anti-insulin receptor antibodies)
<ul style="list-style-type: none"> <li>Other genetic syndromes sometimes associated with diabetes</li> </ul>	Chromosomal abnormalities increase the risk β-cell destruction. (Klinefelter's syndrome, down's syndrome)
<b>Unclassifiable diabetes</b>	Describes diabetes which does not fit clearly in other categories. It is used temporarily when there is no clear diagnostic category, especially close to time of diagnosis
<b>Hyperglycemia first detected during pregnancy</b>	
<ul style="list-style-type: none"> <li>Diabetes mellitus in pregnancy</li> </ul>	Type 1 or 2 Diabetes initially diagnosed in pregnancy
<ul style="list-style-type: none"> <li>Gestational diabetes mellitus</li> </ul>	Hyperglycemia below diagnostic thresholds of diabetes, during pregnancy

## APPENDIX VI: KIDNEY DISEASE IMPROVING GLOBAL OUTCOMES

### CLASSIFICATION OF KIDNEY DISEASES AND DISORDERS<sup>3</sup>.

	<b>Functional Criteria</b>	<b>Structural Criteria</b>
<b>AKI</b>	Serum Creatinine increment by 50% within 7 days or increase in Serum Creatinine by 0.3mg/dl within 2 days, or oliguria	No criteria
<b>CKD</b>	GFR <60 mL/min for >3 months	Kidney damage for >3 months
<b>AKD</b>	AKI, or GFR<60 mL/min/1.73 m <sup>2</sup> for <3 months. Or decrease in GFR by ≥35% or increase in serum creatinine by >50% for <3 months	Kidney damage for <3 months
<b>NKD</b>	GFR ≥60 mL/min/1.73 m <sup>2</sup> , Stable Serum Creatinine	No damage

**APPENDIX VII: KIDNEY DISEASE IMPROVING GLOBAL OUTCOME**

**CLASSIFICATION OF ACUTE KIDNEY DISEASE<sup>40</sup>.**

<b>AKI Staging</b>		
<b>Stage</b>	<b>Serum Creatinine Criteria</b>	<b>Urinary Output Criteria</b>
1.	1.5-1.9 times baseline OR Increase of $\geq 0.3$ mg/dl ( $\geq 26.5$ $\mu$ mol/l)	<0.5ml/kg/h for 6-12 hours
2.	2.0-2.9 times baseline	<0.5 ml/kg/h for $\geq 12$ hours
3.	3.0 times baseline OR Increase to $\geq 4.0$ mg/dl ( $\geq 353.6$ $\mu$ mol/l) OR RRT initiation OR In patients <18 years old, a decrease in eGFR to <35 m/L/min per 1.73m <sup>2</sup>	<0.3 mL/kg/h for $\geq 24$ hours OR Anuria for $\geq 12$ hours

CKD, is also further classified by KDIGO based on cause, estimated GFR and albuminuria category as follows.

## APPENDIX VIII: KIDNEY DISEASE IMPROVING GLOBAL OUTCOME


### CLASSIFICATION OF CHRONIC KIDNEY DISEASE<sup>20</sup>.

<b>STAGE</b>	<b>eGFR (mL/min/1.73m<sup>2</sup>)</b>	<b>DESCRIPTION</b>
G1	≥90	Normal or high
G2	60 - 89	Mildly decreased
G3a	45 - 59	Mildly to moderately decreased
G3b	30 - 44	Moderately to severely decreased
G4	15 - 29	Severely decreased
G5	<15	Kidney failure
<b>Albuminuria STAGE</b>	<b>AER (mg/g)</b>	<b>DESCRIPTION</b>
A1	<30	Normal to mildly increase
A2	30 - 300	Moderately increased
A3	>300	Severely increased

**APPENDIX IX: KAIRUKI UNIVERSITY INSTITUTION REVIEW ETHICAL COMMITTEE REPORT.**

**HUBERT KAIRUKI MEMORIAL UNIVERSITY (HKMU)**

70 Chwaku Street,  
Mikocheni,  
P.O BOX 65300,  
Dar es Salaam,  
Tanzania.



Tel: +255-22-2700021/4  
Fax: +255-22-2775591  
Email: [irec@hkmu.ac.tz](mailto:irec@hkmu.ac.tz)  
Website: [www.hkmu.ac.tz](http://www.hkmu.ac.tz)

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**Ref. No. HKMU/IREC/27.10/438** **09<sup>th</sup> April 2024**

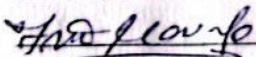
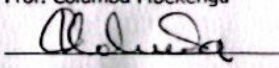
Dr. Consolata D. Kakoko,  
Hubert Kairuki Memorial University,  
P.O. Box 65300,  
**Dar es Salaam, Tanzania.**


**RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING HEALTH RESEARCH.**

I am pleased to inform you that the research titled: **Clinical Biochemical Indicators of Kidney Disease among Newly Diagnosed Diabetes Mellitus Type 2 Adults Attending Diabetic Clinics in Dar Es Salaam (Kakoko C.D., 2024)** has been granted ethical approval.

This approval is in effect for one year from the above date. Any changes in the procedures should be reported to the Institutional Research Ethics Committee. Significant changes will require the submission of a revised request for ethical approval. You will be required to submit **study progress report** every six months.

Permission to publish your findings should be sought from the National Institute for Medical Research (NIMR) before submission to a publisher and not concurrently.

<b>CHAIR PERSON</b>	<b>SECRETARY</b>
Name: Prof. Fredrick Kaijage	Name: Prof. Columba Mbekenga
Signature: 	Signature: 



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**APPENDIX X: PERMISSION LETTERS FOR DATA COLLECTION FROM  
REGIONAL REFERRAL HOSPITALS**



**JAMHURI YA MUUNGANO WA TANZANIA  
WIZARA YA AFYA,  
HOSPITALI YA RUFAA YA MKOA YA TEMEKE**

Barua@pepe.temakehfh@afya.go.tz, S.L.P 45232 Dar es Salaam, Simu 0222856007



Kumb. Na. TRRH/RSC/9/10/11

Tarehe: 22/04/2024

Ndg Consolata Deuseddit Kakoko  
Hubert Kairuki Memorial University (HKMU)  
S L P 65300,  
**DAR ES SALAAM,**

**YAH: OMBI LA KUFANYA UTAFITI "CLINICAL BIOCHEMICAL INDICATORS OF  
KIDNEY DISEASE AMONG NEWLY DIAGNOSED DIABETES MELLITUS TYPE 2  
ADULTS ATTENDING DIABETIC CLINICS IN DAR ES SALAAM" (RESEARCH)**

Tafadhali husika na somo tajwa hapo juu.

2. Nimepokea barua yako ya tarehe 15 Aprili, 2024 kuhusu ombi lako la kufanya Utafiti (Research) katika Taasisi yetu, kuhusu "Clinical Biochemical Indicators of kidney disease among newly diagnosed diabetes mellitus type 2 adults attending diabetic clinics in Dar es Salaam".
3. Ombi lako limekubaliwa, utatakiwa kulipa ada ya utafiti kiasi cha **Tshs.100,000/=** Hivyo wasiliana na mhasibu wa mapato wa Hospitali Ndg. **Lusajo Nsajigwa** kwa namba **0717 959495** ili akupatie control Number kwa ajili ya malipo ya ada hii ili uweze kuruhusiwa kufanya utafiti.
4. Asante kwa ushirikiano.

Dkt. Husna Msangi  
Kny: **MKURUGENZI**

**HOSPITALI YA RUFAA YA MKOA YA TEMEKE**

Nakala: Kiongozi CSCO/Internal Medicine -

*Tafadhali hakikisha taarifa  
ya utafiti inabaki hospitalini*

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THE UNITED REPUBLIC OF TANZANIA  
MINISTRY OF HEALTH

Telephone Address:  
Telephone: 022-2760500



Mwananyamala Regional  
Referral Hospital,  
P O Box 61665  
Dar es Salaam

RE: NO.: MA. 239/240/01/102

DATE: 23<sup>TH</sup> April, 2024

Director,  
Hurbert Kairuki Memorial University,  
P O BOX 65300,  
DAR ES SALAAM.

**RE: DR. CONSOLATA DEUSDENIT KAKOKO - TO CONDUCT HIS RESEARCH IN  
MWANANYAMALA REGIONAL REFERRAL HOSPITAL**

The captioned subject refers

2. May you be informed that your request to research Titled "*Clinical Biomedical indicators of kidney disease among newly diagnosed diabetes mellitus type 2 adults attending diabetic clinics in Dar es Salaam*" Start to 23<sup>th</sup> April, 2024, to 22<sup>th</sup> Mei, 2024 is asserted.

3. The Institution charges 50,000/= as Research fee as per student spent. The payments are to be made upon reporting.

4. May she report to the Administration and HR department head for further instruction.

Thanks.

Dr. Mkiwa A. A. A.  
RESEARCH COORDINATOR  
FOR: MEDICAL OFFICER IN CHARGE  
MWANANYAMALA REGIONAL REFERRAL HOSPITAL



COPY:  
Heads of Internal Medicine Department - MWANANYAMALA REGIONAL  
REFERRAL HOSPITAL

Dr. Consolata Deusdeit Kakoko - Report to the head of Internal Department



THE UNITED REPUBLIC OF TANZANIA  
MINISTRY OF HEALTH

AMANA REGIONAL REFERRAL HOSPITAL



Telegram "HEALTH", DODOMA  
Phone No. : +255 028 - 2323267  
Email: [pe@alya.go.tz](mailto:pe@alya.go.tz)

P.O. Box 25411  
DAR ES SALAAM  
Phone: 022-2861903

REF. NO. MeHCDEGEC/ARRHR.1/VOL II/36

Date: 16/04/2024

Directorate of Research,  
Publications and Innovations,  
MUHAS,  
P.O. Box 65001,  
DAR ES SALAAM.

**Re: PERMISSION FOR DATA COLLECTION**

Refer to your letter dated 15<sup>th</sup> April, 2024 which requested us to allow **Dr. Consolata Deuseddit Kakoko** to conduct research and collect data in our institution.

We are here to acknowledge your request with the following conditions, that she must submit the results of her research after completion of analysis in order the hospital to make use of data's to solve hospital problems.

Regards.


For:  
MEDICAL OFFICER I/C  
AMANA REGIONAL REFERRAL HOSPITAL  
P. O. Box 25411  
DAR ES SALAAM

*Dr. Rose Ntambito*

FOR: MEDICAL OFFICER INCHARGE  
AMANA REGIONAL REFERRAL HOSPITAL

(All Correspondence should be directed to Medical Officer Incharge)  
Email: [amana@amanarrh.go.tz](mailto:amana@amanarrh.go.tz), Website: [www.amanarrh.go.tz](http://www.amanarrh.go.tz)

## APPENDIX XI: TURNITIN PLAGIARISM REPORT

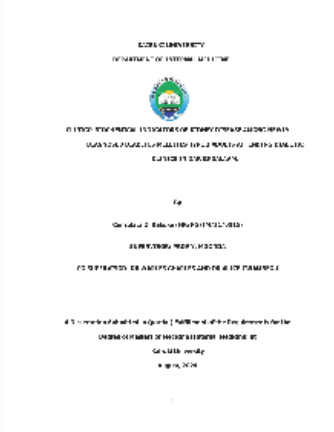


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Page count: 80  
Word count: 12,712  
Character count: 73,287  
Submission date: 14-Aug-2024 04:44PM (UTC+0200)  
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The image shows the cover page of a document. At the top, it reads 'UNIVERSITY OF UYO' and 'FACULTY OF HEALTH SCIENCES'. Below that is the 'UNIVERSITY OF UYO' logo. The main title is 'CLINICO-BIOCHEMICAL INDICATORS OF KIDNEY DISEASE A...'. Below the title, it says 'BY' and 'CONSOLATA KAKOKO'. At the bottom, it says 'SUBMITTED TO THE DEPARTMENT OF MEDICAL LABORATORY SCIENCE' and 'BY' and 'CONSOLATA KAKOKO'.

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Info

Submission Details

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Class Name	MMED 2020-202
Class ID	35515116
Submission ID	2431993693
Submission Date	14-Aug-2024 04:44PM (UTC+0200)
Submission Count	2
Last Graded Date	14-Aug-2024 04:45PM (UTC+0200)
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Comments	N/A
Grammar marks	N/A
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