AN AUDIT OF CARDIOVASCULAR RISK MANAGEMENT IN TYPE 2 DIABETES MELLITUS AT KENYATTA NATIONAL HOSPITAL.

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Declaration

I, Dr. Simeon O. Jowi, declare that this is my original work and that it has not been presented before for a degree or any other academic award at this or any other university.

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List of abbreviations and acronyms

ACC – American college of cardiology

ADA – American Diabetes Association

AHA – American Heart Association

ASCVD – Atherosclerotic Cardiovascular Disease

BMI – Basal Metabolic Index

BP – Blood Pressure

BPH – Benign Prostatic Hyperplasia

CAD – Coronary Artery Disease

CV - Cardiovascular

CVD – Cardiovascular disease

DM – Diabetes Mellitus

D.O.B – Date of Birth

DOPC – Diabetic Outpatient Clinic

EASD – European Association for the Study of Diabetes

ECG- Electrocardiogram

ESC – European Society of Cardiology

GLP1-Ra - Glucagon Like Peptide1-Receptor agonist

HAART – Highly Active Anti-Retroviral Therapy

HbA1c – Glycated Haemoglobin

HF – Heart Failure

HIC – High Income Countries

HDL-C - High density lipoprotein cholesterol

HMIC – High and Middle income countries

HMG-COA - β-Hydroxy β-methylglutaryl-CoA

HTN - Hypertension

IDF – International Diabetes Federation

KNH – Kenyatta National Hospital

LDL-C – Low density lipoprotein cholesterol

LIC – Low Income Country

LMIC – Low and Middle Income Countries

RAAS - Renin Angiotensin Aldosterone System

SSA – Sub Saharan Africa

SGLT2 – Sodium Glucose Cotransporter-2

T2DM – Type 2 Diabetes Mellitus

UK – United Kingdom

UKPDS- U.K. Prospective Diabetes Study

US – United States

USD - United States Dollar

ABSTRACT

Background: Type-2-diabetes-mellitus (T2DM) is the commonest form of DM worldwide and is associated with long-term complications. Adequate control of cardiovascular (CV) risk factors in T2DM is associated with up to a 50% decrease in risk of cardiovascular and microvascular events. Local studies show that specific CV risk factors in T2DM are prevalent but inadequately controlled.

Objectives: To determine the adequacy of management of cardiovascular risk and healthcare practitioner's knowledge of management of cardiovascular risk among T2DM patients at Kenyatta National Hospital.

Materials and Methods: A cross-sectional study with a retrospective and a prospective component was done at Kenyatta National Hospital (KNH). The study areas were the diabetes outpatient clinic, its decentralized records department, and the medical wards. The study involved 74 healthcare practitioners chosen by non-probability purposive sampling and 362 T2DM patient files chosen by systematic random sampling.

Results: Of the 362 study subjects: 68% were female, the median age was 59.0 (IQR 50.0 – 67.0) years, the median duration of diabetes was 9 (IQR 4-14) years, and the majority (47.8%) had had two clinic visits during the period of study. Risk-stratification indicated high risk in 57.7% of the study group. Eighty-one (81.5%) had hypertension, and 87.8% of these were on a RAAS blockade-based regimen. Two-thirds (67.5%) of these had off-target BP readings. Only 43.6% of patients with T2DM had documented HbA1c results, and only 34.8% were within the target range as per guidelines. About half (56.9%) of the study group had lipid profiles requested within the previous 12 months; none had documented specified targets for LDL control. The use of an antiplatelet agent for appropriate primary and secondary prevention of atherosclerotic cardiovascular disease (ASCVD) was at 14.6% and 66.7% respectively. Assessment of healthcare practitioners' knowledge on CV risk management in T2DM revealed a below-average level. The internal-medicine-residents' mean score was 39%, the clinical-officers score was 36.4% and the medical-officers' mean was the lowest at 27%.

Conclusion: There was an overall low performance across most aspects of CV risk management as shown by both audit arms. We, therefore, concluded that CV risk factor management was inadequate, likely due to insufficient knowledge on current guideline-directed management.

CHAPTER ONE

Introduction

Diabetes mellitus (DM) is a long-term condition that typically comes about when blood glucose levels are elevated either due to inadequate insulin production or due to inefficacious use of the available insulin. It is emerging as one of the major healthcare challenges of modern times. Globally, type 2 diabetes mellitus (T2DM) is the most prevalent form of DM(1).

T2DM, when not adequately managed, is associated with long-term complications. These can either be microvascular such as retinopathy and neuropathy or macrovascular such as cardiovascular disease. DM has been demonstrated to be a significant risk factor for cardiovascular disease (CVD). Furthermore, diabetics have significantly higher cardiovascular morbidity and mortality and are inordinately affected by CVD compared to non-diabetics(2). These cardiovascular diseases account for the majority of mortalities in T2DM patients(3). Cardiovascular disease in DM is rising globally(1) with similar trends being observed in the developing countries(4). This puts a great financial strain on both the patients and the healthcare system with global estimates in absolute numbers anticipated to increase from USD $1.3 trillion as of 2015 to approximately USD $2.1 to $2.5 trillion by 2030(5).

Cardiovascular complications of diabetes, particularly those of macrovascular nature such as atherosclerotic cardiovascular disease are as a result of chronic hyperglycemic state, saddled with a high burden of cardiovascular risk factors such as smoking, obesity, hypertension and dyslipidaemia(3). Available literature supports the fact that control of these multiple risk factors in patients with type 2 diabetes is associated with up to a 50 % decrease in the risk of cardiovascular and microvascular events(6). Despite this widely available knowledge, local studies done at the KNH by Otieno et al. and in Nyeri by Kimando et al. respectively, have shown that specific cardiovascular risk factors of T2DM are prevalent but not adequately controlled to targets(7,8).

This study's main objective was to audit the quality of cardiovascular risk management in T2DM and to determine knowledge of healthcare practitioners on cardiovascular risk factors and their control at KNH.

CHAPTER TWO

2. Background and literature review

2.1 Definitions.

Diabetes mellitus (DM) is a serious long-term condition; it typically comes about when a person's body, either can't produce any or enough insulin or can't effectively use the insulin it produces, resulting in elevated blood glucose levels. In type 2 diabetes, hyperglycemia is initially the result of insulin resistance but is also associated with impaired insulin secretion(1).

2.2 Epidemiology.

DM poses a significant public health challenge. As of 2019, statistics from the International Diabetes Federation (IDF) estimate that roughly 463 million adults are diabetic; by 2045 this number will be expected to have risen to 700 million(1).

In Sub Saharan Africa (SSA), as of 2019, 19 million people were estimated to be living with DM. The figure is anticipated to grow by 143% to 47 million individuals by 2045. Globally, T2DM is the most prevalent form of DM(1). As of 2019, it accounted for approximately 90% of worldwide cases, with similar statistics being replicated in data from SSA. Locally, earlier estimates of the prevalence of diabetes by Kenya 2015 national STEPs survey showed a prevalence of 1.9% (males 1.5%, females 2.3%), while IDF (2019) estimates put the prevalence of DM in adults in Kenya to be at 2.2%(1,9). These figures were lower than those from local population based studies carried out in higher burden areas(both rural and urban) which reported higher DM prevalence of 3.5-5%, as compared to the STEPS data which averages the whole country, with higher proportions seen in the urban areas as compared to rural areas(10).

As previously mentioned, T2DM is associated with protracted complications which are continuously increasing among patients residing in the developing world. Besides microvascular complications such as retinopathy and neuropathy, CVD with its accompanying morbidity and mortality, is rising in developing countries(4).

2.3 Classification of diabetes mellitus

As per the IDF 2019 Diabetes Atlas, diabetes is classified as(1):

- Type 1 DM: is due to an autoimmune reaction whereby the body's immune system targets the pancreatic beta cells responsible for producing insulin.
- Type 2 DM:
  Elevated plasma glucose levels are the result of insulin resistance; subsequently, over time, inadequate insulin production can develop as a result of failure of the pancreatic beta cells to sustain the demand for insulin.
- Gestational diabetes:
  Diabetes diagnosed in the second or third trimester in a woman who was previously not known to have diabetes.
- Other forms of diabetes:
  Include: Endocrinopathies (thyrotoxicosis, Cushing's syndrome and acromegaly), infections, genetic disorders, diseases of the exocrine pancreas (pancreatitis, Ca pancreas) and drugs (corticosteroids. anti-psychotics, HAART).

2.4 Cardiovascular disease and type 2 diabetes mellitus.

Cardiovascular diseases (CVD) are the most prevalent complications in patients with T2DM. Globally, it is estimated that CVD affects approximately 32.2% of people with T2DM in high income countries (HIC) and middle income countries (MIC)(11), with some studies showing that the relative risk of CVD in T2DM is increased 3.5-fold(12).

Atherosclerosis is the most common complication with it and its consequent manifestations such as CAD, stroke and peripheral arterial disease being the most prevalent CVD complications. Studies have reported prevalence rates as 29.1% for atherosclerosis and prevalence rates of 21.2% and 7.6% for its complications of CAD and stroke respectively(11).

In addition to that, people with T2DM have a higher cardiovascular morbidity and mortality and are disproportionately affected by CVD compared to those without it. In the diabetic population, there is a two to four-fold rise in the occurrence of CAD and cerebrovascular disease and a two to eight-fold rise in heart failure risk(13). In these patients, CVD is a significant cause of mortality being responsible for approximately 50.3% of all deaths(12, 14).

Cardiovascular complications of DM, especially those of macrovascular nature usually result from chronically elevated blood glucose levels in connection with established cardiovascular risk factors such as smoking, obesity, dyslipidaemia and hypertension. These complications are found to occur earlier in the DM population as compared to the non-DM one. Even before attaining adequate levels for a diagnosis of DM, the risk of CVD increases unremittingly with rising fasting plasma glucose levels(3,14). Currently, there is inadequate data on cardiovascular disease prevalence in T2DM patients in SSA.

2.5 Cardiovascular Diseases and type 2 diabetes mellitus

2.5.1 Coronary Artery Disease and T2DM.

According to studies in High and Middle Income Countries (HMIC), prevalence of coronary artery disease (CAD) and atherosclerosis were at rates of 21.2 and 29.1% respectively in type 2 diabetics. Of the quoted 50% mortality attributable to CVD in T2DM, CAD contributed to 29.7%(11). As earlier mentioned, available data demonstrates that diabetic vascular disease is accountable for a two-four-fold increase in CAD occurrence(13). Furthermore, T2DM significantly increases the risk of mortality in CAD(15). Haffner et al demonstrated that diabetics have the same risk of having a new MI as a non-diabetics having had a previous MI and that if one has both diabetes and a previous MI, then risk is multiplied. This translated to increased death rates due to cardiovascular causes in patients with T2DM at 15.4% for those without prior MI and 42.0% with prior MI, in contrast, non- T2DM patients had death rates of 2.1% in those without prior history of MI and 15.9% in those with prior history of MI(16). Finally, diabetic patients with MI tend to have higher mortality compared to their non-diabetic counterparts with MI(17,18).

Locally, a study carried out at the Nairobi Hospital in 2002-2003, by Kamotho et al found DM to be the most strongly associated risk factor in the population with angiographically detected CAD, it being present in 38.5% of that population(19). The study of CAD in SSA is limited by a general deficiency of diagnostic facilities. Conservative estimates put the prevalence of ischemic heart disease in DM at between 5% and 8%. This is much lower than documented rates in HICs(20).

2.5.2 Stroke and T2DM

T2DM is a strong predictor of cerebrovascular disease. Cerebrovascular accidents are one of the major macrovascular complications associated with the increased cardiovascular risk attributable to type 2 DM(21). T2DM is also associated with poorer prognosis compared to the normal stroke population due to its association with: heightened recurrent stroke risk, greater functional disability, lengthened in-patient stay and increased mortality. In terms of aetiology, the majority of these strokes, close to 80% are usually due to an ischaemic process(22).

Globally, a meta-analysis approximated the DM prevalence in all stroke inpatients to be 28% (95% CI 26–31). When HbA1c was the sole criteria for diagnosis of DM, the prevalence of strokes was 37%(23). Data solely from HMIC countries reported the prevalence rates of strokes among all CVD in type 2 DM patients to be at 7.6%. These strokes resulted in 11.0% of all deaths attributable to CVD in T2DM(11). Closer home, in SSA, a study carried out on a diabetic population in Sudan found stroke prevalence to be at 5.5%(24). In Tanzania, available data showed that 4.4% of T2DM patients presented with a stroke at diagnosis(25). Locally, a prospective multicenter cohort study among stroke patients found that the prevalence of diabetes was 14.9% (males: 15.7%; females: 14.4%)(26).

2.5.3 Peripheral Arterial Disease and T2DM.

Global estimates posit that 20%-30% of patients with peripheral artery disease (PAD) have DM(27). However, this is a likely underestimation due to the asymptomatic nature of less severe PAD and the altered pain perception in diabetic patients due to peripheral neuropathy. This data also found that DM is associated with more severe below-the-knee PAD(27). Closer home, a Nigerian study found a prevalence of PAD at 52.5% in the diabetic population(28). A local study by Nikita et.al documented a 43% prevalence of DM among patients with asymptomatic PAD at KNH(29).

2.5.4 Heart failure and T2DM

DM patients have over twice the risk of developing heart failure (HF) than their non-diabetic counterparts(30). T2DM is associated with HF independently of age, race, hypertension or the other established risk factors(31). HF and T2DM often occur concomitantly, with each disease independently increasing the risk for the other(32). Studies also demonstrate that, in hospitalized patients receiving similar care,T2DM is associated with: worse prognosis(33), increased risk for

combined CV mortality and HF-related hospitalization (34), and longer hospital stay compared to non T2DM patients(33–36).

DM is thought to cause a diabetic cardiomyopathy with ventricular dysfunction that occurs in the absence of CAD and hypertension, it is associated with increased susceptibility of the myocardium to dysfunction characterized by functional and structural abnormalities, such as left ventricular hypertrophy, fibrosis and cell signaling abnormalities that confer a higher risk of developing the aforementioned diabetic cardiomyopathy(37,38). Available data from a meta-analysis reflecting a global picture reported a prevalence rate of HF in T2DM as approximately 14.9%(11). While available data solely from HIC demonstrated a diabetes prevalence of between 20% and 40% of all patients with heart failure(32, 33).

2.6 Economic burden of cardiovascular disease in T2DM.

CVD in T2DM patients disproportionately increases the cost of managing the disease. These costs are borne both directly by the patients and indirectly by public health systems. Available data from a 2018 systematic review from LMICs estimate that, CVD costs accounted for between 20% and 49% of the total direct costs of treating T2DM. The median annual costs per patient for CVD, and its components such as CAD, HF, and stroke were approximated to be at, 112%, 107%, 59%, and 322% respectively higher in T2DM patients with CVD compared to those without. In terms of concrete figures, this resulted in a cost increment ranging from $3418 to $9705 treating patients with both CVD and T2DM compared to treating patients with T2DM alone(39).

2.7 Cardiovascular risk factors in T2DM and outcomes of risk factor management.

2.7.1 Cardiovascular risk factors

Hypertension (HTN) is present in more than 50% of patients with DM, with a prevalence of up to three times higher in diabetics compared to their non-diabetic counterparts(40). It contributes substantially to macrovascular disease in DM. Patients with both DM and HTN have a two to four-fold CVD risk when matched with normotensive non-diabetic controls(41,42). Local studies show, approximately, a 50% prevalence of HTN in the T2DM population(7,8).

Obesity or being overweight is known to substantially increase the risk of getting T2DM, cardiovascular disease, cancer and premature death. Obesity and being overweight are a common

finding in T2DM patients with global prevalence rates of about 80%(43,44). These conditions have additionally been linked with poor cardiovascular risk factor control among T2DM patients(45). Moreover, it has also been shown that in T2DM, obesity increases the risk of CVD(11).

Hyperglycaemia or poor glycaemic control in T2DM is linked with heightened CVD mortality(46). Evidence for a causative relationship between plasma glucose levels and macrovascular disease is considerably weaker in comparison to that for microvascular disease. However, there is available evidence demonstrating poor glycemic control to be a risk factor for macrovascular disease(47). With regards to measured plasma glucose levels, it has been shown that post-prandial glucose levels rather than fasting glucose levels, not only provide better information about future CVD risk, but also predict increased cardiovascular risk in subjects with otherwise normal fasting glucose levels(48). As pertaining to HbA1c levels, some studies have shown an associated 40% increase in CVD mortality and 30% increase in all-cause mortality for every 1% rise(49).

However, it is worthwhile to point out that evidence from the RCTs that had examined intensive glucose lowering strategies and the subsequent effect of on macrovascular risk, were initially conflicting(50,51) however, much is changing with the advent of newer drugs such as sodium–glucose cotransporter-2(SGLT2) inhibitors and glucagon like peptide1-receptor agonists (GLP1-Ra) which have been shown to have a mortality benefit in CVD(52–55). A local study assessing adequacy of control of cardiovascular risk factors in T2DM found prevalence of poor glycaemic control, determined as a HbA1c above 7%, to be at 60.5%(8).

Microalbuminuria is defined as albumin levels ranging from 30 to 300 mg in a 24-h urine collection while overt albuminuria, macro-albuminuria, or proteinuria is defined as a urinary albumin excretion of ≥300 mg/24h(56). A strong association has been elucidated between albuminuria and cardiovascular outcomes in T2DM patients. Available data from the Heart Outcomes Prevention Evaluation (HOPE) study found that any degree of albuminuria is considerable as a risk factor for cardiovascular events in patients with or without DM(57). Available local data stated the prevalence of albuminuria in T2DM to be at 32.7%(8).

Dyslipidemia is another major cardiovascular risk factor in T2DM patients. Globally, it affects almost 50% of patients with T2DM, while the most recent available local data intimates a much higher prevalence of 77.1%. It is characterized by elevated triglyceride levels, low high-density

lipoprotein cholesterol levels (HDL-C), and a prevalence of small, dense, low-density lipoprotein particles (LDL-C)(8,58). Dyslipidaemia is a major risk factor for macrovascular complications in this population of patients, with elevated LDL-C as the major culprit in terms of risk for CVD and therefore, its rigorous management should be a primary goal of management in CVD prevention(41,59,60).

Cigarette smoking is a proven risk factor for T2DM(61,62). Available data from a 2014 US report suggests that smoking raises T2DM risk by 30–40% for active smokers compared to non-smokers(63). Another study also showed smoking to be independently linked with higher HbA1c concentrations, demonstrating a 0.12% HbA1C rise per 20 pack-years in both sexes(64). Concerning CVD, available data shows that current smoking is significantly and independently a risk factor for all-cause mortality, CAD mortality and CVD mortality(65). With regards to prevalence in T2DM ,local population based studies of cardiovascular risk factors in this population by Otieno et al. and Kimando et al. showed prevalence rates of 15% and 23.6% respectively(7,8).

2.7.2 Outcomes of guideline directed management of cardiovascular risk in T2DM.

As previously stated, glycaemic control has a more significant role to play in prevention of microvascular complications. In terms of macrovascular complications, some studies have demonstrated that, with regards to controlling glycaemia, newer agents such as sodium–glucose cotransporter-2 inhibitors (SGLT2) and glucagon like peptide1-receptor agonists (GLP1-Ra) which have proven CV benefits in established CVD may also have benefit in primary prevention of CVD in T2DM patients, particularly those at high risk(52–55,66,67).

Several studies have demonstrated that effective management of dyslipidaemia effectively reduces cardiovascular events in at risk populations such as T2DM(41,68,69). As for hypertension, studies have also shown a similar pattern of reduction of cardiovascular events with adequate control(70).

All in all, CV risk should be managed aggressively in T2DM patients since cardiovascular outcomes are often poorer in this population when matched with non-T2DM patients. It is essential to implement multifactorial interventions targeted at the multiple risk factors because available data shows that target-driven, long-term, intensified intervention aimed at these multiple risk factors reduces the risk of cardiovascular and microvascular events by about 50 percent(6).

2.8 Guideline directed management of cardiovascular risk in T2DM.

Given the acknowledgment of cardiovascular risk factors in T2DM and the serious morbidity and mortality attributable to CVD in these patients, multiple guidelines and standards of medical care in diabetes mellitus have been developed. These standards of care are initially selected from clinical guidelines supported by the highest level of evidence available. Different regions/countries around the world tend to tailor make their own guidelines. However, most guidelines surrounding cardiovascular risk management in T2DM tend to cover the following risk factors/areas:

- Hypertension
- Dyslipidaemia
- Obesity/overweight
- Smoking cessation
- Lifestyle modification(including diet, exercise and alcohol use)
- Use of anti-platelets

This guideline directed management is dynamic and is revised as new evidence becomes available.

2.9 Various guidelines for cardiovascular risk management in type 2 DM

For this audit we referred to the following guidelines with respect to standards of care for each risk factor:

- Kenya National Clinical Guidelines for the management of Diabetes Mellitus
- American Diabetic Association(ADA) (71,72)
- Joint consensus report of European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD) (73)

For the sake of completeness and giving a background to our audit tool, we broadly compared and contrasted the above the guidelines in terms of management to highlight any differences/ similarities as shown in table 1. Of note is that this audit was for the most part be based on consensus of the three guidelines and where there was a discrepancy we stuck to our local guidelines. The local guidelines referenced were listed in the appendices (Appendix 5.4).

Table 1: Comparison of consensus within the guidelines with respect to key areas of cardiovascular risk management in T2DM (see Appendix 5.4 for actual figures involved)

Risk Factor/ Standard of care	**Kenya diabetic clinical guidelines**	**ADA**	**ESC/EASD**
Risk stratification ADA and ESC have different methods of quantifying variables while stratifying risk however treatment targets based on risk stratification are similar	Kenya guidelines borrow aspects of risk stratification heavily from ESC**: moderate, high, very high**	**ADA uses a risk stratification based on the ACC 10yr ASCVD risk calculator that stratifies risk in terms of %s. e.g 10%,15%, >20%**	**Stratified as moderate, high risk and very high risk**
Hypertension	Target <**140/80**	Target **<140/90** Target **130/80** for high CV risk	Target ≤ **130/80** For most diabetics
Dyslipidaemia (Largely based on risk stratification)	Target LDL Moderate risk = **<2.6mmol/l** High risk = **< 1.8mmol/l** Triglycerides **<1.7mmol/l**	Target LDL **<2.6mmol/l** **Triglycerides <1.7mmol/l**	Target LDL Moderate risk = **<2.6mmol/l** High risk = < **1.8mmol/l** Very high risk =<**1.4mmol/l**
Glycaemic control	**HbA1c target <7** Less stringent in elderly **< 8**	**HbA1c target <7** Less stringent in elderly **< 8**	**HbA1c target<7** Less stringent in elderly **< 8**
Smoking	Cessation is obligatory	Cessation is obligatory	Cessation is obligatory
Obesity/Overweight	Target BMI <25kg/m2 Target 10% weight loss	Target BMI <25kg/m2 Target > 5% weight loss	Target BMI <25kg/m2 Target 5-10% weight loss

Risk Factor/ Standard of care	Kenya diabetic clinical guidelines	ADA	ESC/EASD
Lifestyle modification ✚	Individualised diet models with aim of reduced caloric intake Moderate to vigorous >150min combined aerobic+ resistance exercise weekly	Individualised diet models with aim of reduced caloric intake Moderate to vigorous >150min combined aerobic+ resistance exercise weekly	Individualised diet models with aim of reduced caloric intake Moderate to vigorous >150min combined aerobic+ resistance exercise weekly
Use of anti-platelets ✚	May be used in T2DM patients at high/very high risk(without contraindications or increased risk of bleeding)	May be used in T2DM patients at high/very high risk(without contraindications or increased risk of bleeding)	May be used in T2DM patients at high/very high risk(without contraindications or increased risk of bleeding)

Key: ✚ represents consensus/similarities in the guidelines

2.10 Audits on cardiovascular risk factor management.

Despite the knowledge that cardiovascular risk factor control helps reduce CVD, some aspects of CV risk factor control are still being underutilized. Generally, there is scarce data available on studies holistically auditing adherence to guidelines on CV risk in T2DM. Instead, available data tends to be from studies assessing a particular component of cardiovascular risk.

For example, for dyslipidaemias, some Scandinavian studies on use of lipid lowering agents exposed discrepancies between the recommended lipid-lowering drug therapy and current practice especially for primary prevention, with a substantial under-treatment noted(74). For one of these studies by Karlsson et.al, they also found that patient non-adherence to guideline directed prescription was also a major factor in non-compliance(75).

An audit on cardiovascular risk assessment in the UK on T2DM patients referred for insulin therapy exposed significant under-recognition of the high vascular risk within the T2DM population with regards to prescribing patterns, as compared to their current guidelines for primary and secondary prevention and evidence based practice(76).

An American study assessed physician's awareness and adherence to cardiovascular disease prevention guidelines and found some gender-based disparity in risk assessment (for women subjects). Physicians didn't rate themselves as quite effective in their ability to help prevent CVD(77).

A Malaysian study auditing control of hypertension in diabetics found that less than half of DM cases registered in their audit of diabetes control and management registry achieved good control of BP to their target level of ≤130/80 mmHg. They also found that antihypertensive treatments were mainly monotherapy, as opposed to recommended combination therapy, however the commonly prescribed antihypertensive drug was ACEI which was at least in line with their guidelines. The overall recommendation was that their physicians prescribing skills for management of HTN in T2DM patients required further improvements(78).

2.11 Problem statement

Due to the large burden of type 2 DM on society as a whole, there's significance in adequately managing it and preventing its serious cardiovascular complications and their sequelae. Moreover, cardiovascular disease is the leading cause of death in people with diabetes mellitus(11,71).

We have local data showing that despite prevalence of these cardiovascular risk factors in T2DM patients, we are doing poorly in terms of cardiovascular risk factor control(7,8). What we don't have is adequate data to try explain why that is the case. Through clinical audit and subsequent use of the information obtained from the audit, we can improve our CV risk management in T2DM. Consequently, we can go a long way in reducing the incidence of the resultant cardiovascular complications such as stroke and CAD(6,16).

2.12 Conceptual framework

Figure 1 below is a conceptual framework of the study. It attempts to explain the study's aim and the causal relationships between guideline directed management of CV risk factors, prevalence of CV risk factors and development of CVD in T2DM. T2DM patients are already disproportionately affected by these cardiovascular risk factors. Presence of T2DM in addition to CV risk factors significantly increases the risk of developing CVD. Therefore, inadequate guideline directed management of CV risk in T2DM would result in poor cardiovascular risk factor control which would result in increased cardiovascular disease in type 2 DM.

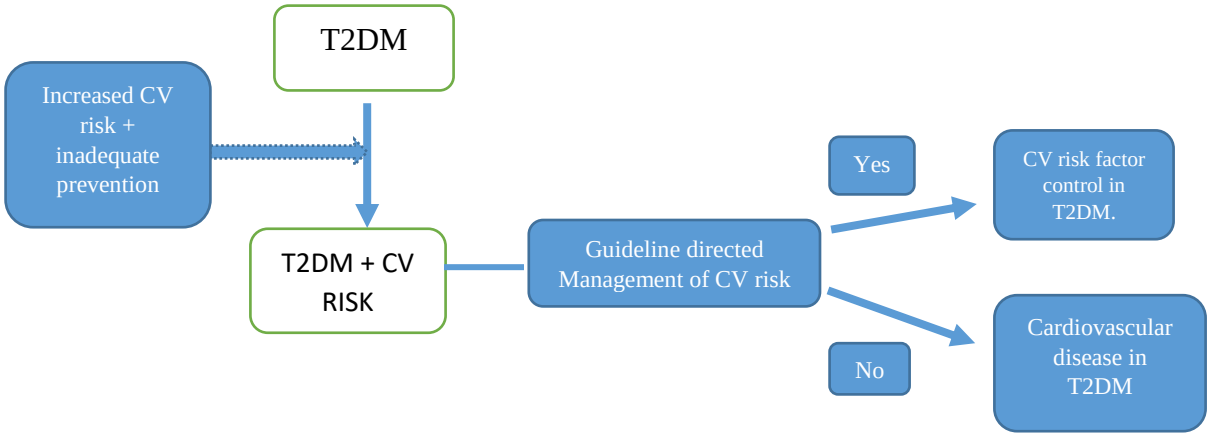


Figure 1: Conceptual framework showing relationship between CV risk factors in T2DM, CV risk factor control and CV disease in T2DM.

2.13 Study justification.

It is worthwhile to find out if our CV risk management is adequate or up-to-date with recommended guidelines and best standards of practice.

Currently, there is no similar study that has been done in our country hence it is a novel study. Furthermore, we believe that this study will build on the available data by addressing the gaps in the available body of knowledge by auditing the process (guideline directed management of cardiovascular risk by healthcare practitioners) that has led to the current situation or outcome (poor cardiovascular risk factor control) that available data shows.

We believe that this study is significant as it will help to improve on knowledge and practice in management of T2DM patients and that it will also aid with formulation of institutional and departmental policies that will ensure appropriate management of CV risk in T2DM patients.

2.14 Research question.

What is the adequacy of cardiovascular risk management in type 2 DM patients at KNH with respect to current guidelines?

2.15 Study objectives

2.15.1 Broad Objective

To determine, the adequacy of management of cardiovascular risk and healthcare practitioner's knowledge of management of cardiovascular risk among type 2 Diabetes Mellitus patients at Kenyatta National Hospital.

2.15.2 Specific Objectives

- Primary Objectives
    i. To assess the adequacy of cardiovascular risk management in type 2 DM patients (in comparison with current guidelines)
    ii. To audit healthcare practitioners on knowledge of cardiovascular risk factors and their management in type 2 DM.

CHAPTER 3

3. METHODOLOGY

3.1 Study site

The study site was at the Kenyatta National Hospital (KNH). KNH is a national referral hospital in Nairobi, Kenya's capital city. It has a bed capacity of approximately 1800 with its main catchment areas being Nairobi, Central and surrounding Eastern parts of Kenya. KNH is also a teaching institution for both undergraduate and postgraduate medical students and various other disciplines in health.

The main study areas were: the diabetic outpatient clinic, with its decentralized records department and the KNH medical wards. The diabetic outpatient clinic has its own decentralized records department which stores files for patients with diabetes mellitus. This area was vital in providing data that helped us achieve our first primary objective. Finally, the diabetic outpatient clinic and the medical wards provided us with access to the healthcare practitioners primarily involved in management of Type 2 Diabetes Mellitus patients and were, thus, of great value in helping us gather the data to achieve our second primary objective.

3.2 Study design

The study design was cross-sectional with a retrospective and prospective component:

i. A descriptive retrospective audit of files of Type 2 DM patients to assess adequacy of management of cardiovascular risk.
ii. Quantitative cross-sectional survey to assess healthcare practitioners' knowledge on cardiovascular risk factor control among type 2 DM patients.

3.3 Study population

I. File records of type 2 DM patients on follow up at the diabetic outpatient clinic between January 1st 2019 and December 31st 2019.
II. Healthcare Practitioners (medical officers, clinical officers and internal medicine residents) who attend to Type 2 DM patients.

3.4 Case definitions

- The definition of type 2 DM was adopted from the IDF 2019 Diabetes Atlas.

The patients needed to have had evidence of one of the following diagnostic markers at the onset of follow up for the file diagnosis of diabetes to have been made:

a) Fasting plasma glucose levels ≥ 7.0 mmol/l
b) Two hour plasma glucose levels ≥ 11.1mmol/l
c) HbA1c of ≥ 6.5mmol/l
d) Random plasma glucose ≥ 11.1mmol/mol.

- Definition of hypertension was based on documented file diagnosis of hypertension.
- Target BP : < 140/80
- Target HbA1c: <7%
- Target LDL : <2.6mmol/l for moderate risk and < 1.8mmol/l for high risk
- Moderate cardiovascular risk: T2DM patient less than 50 years of age with DM duration of less than or equal to 10 years, without any other additional risk factors.
- High cardiovascular risk: a patient with DM duration of equals to or more than 10 years without target organ damage, plus any other additional risk factor
- Very high cardiovascular risk: DM plus either an established CVD or target organ damage or 3 or major risk factors.

3.4.1 Healthcare practitioners

These were defined as internal medicine residents, clinical officers (stationed at the DOPC), and medical officers who regularly manage Type 2 DM patients or participate in a care plan and the treatment given to the patient.

3.5 Inclusion and exclusion criteria

3.5.1 Inclusion criteria (T2DM patients' files)

i. Files of patients, diagnosed with type 2 DM on follow up at the KNH DOPC for at least a period of one year (the target period of the audit was as of January 1st 2019 to December 31st 2019).

3.5.2 Exclusion criteria (T2DM patients' files)

i. Newly diagnosed patients with less than a year of follow up at the KNH DOPC.
ii. Incomplete or missing file records (records for the target period of the audit are unavailable in the files, meaning, the patient was not seen at any point that year)

3.5.3 Inclusion criteria (Healthcare practitioners)

i. Qualified medical personnel working at KNH at the time of the study, including medical officers, internal medicine residents and clinical officers stationed at the DOPC.

3.5.4 Exclusion criteria (Healthcare practitioners)

i. Health workers who decline to give consent.

3.6 Sample size

3.6.1 Type 2 DM Patients.

As previously mentioned, for the five years ending December 2019, on average, there were 7954 diabetic patient visits annually at the diabetic outpatient clinic. This number included both the main and daily diabetic clinics. It also comprised both type 1 and 2 diabetics.

Since we were unable to obtain concrete data on actual numbers of T2DM from the statistics department we therefore applied global proportions of T2DM as a percentage of all diabetics to help calculate the sample size. This meant, we assumed that 90% of the clinic visits were attributable to T2DM:

(7954*90)/100 = 7158

Files of patients on follow up for at least a year, as of Jan 2019 and seen in the DOPC were targeted for the study.

The sample size for patients was determined using the formula for finite population:

$$n = N*X / (X + N - 1),$$

Where,

$$X = Z_{\alpha/2}^2 *p*(1-p) / MOE^2,$$

Where,

N = size of the target population = 7158 (T2DM clinic visits at the outpatient clinic over a year)

$Z_{\alpha/2}$ = is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96.

P = Prevalence of CV risk factors in our setting (as per the latest study by Kimando et al on CV risk factors in T2DM) =

- 45.6%

MOE = margin of error = 5%

A Finite Population Correction was applied to the sample size formula.

The computed sample size came to:

- 362

Therefore, to get a statistically representative proportion of T2DM we endeavored to audit at least 362 files of T2DM patients on follow up for the year 2019.

3.6.2 Healthcare practitioners

There were approximately 80 internal medicine residents, 8 medical officers in the medical wards and 2 clinical officers trained in diabetes management, at the DOPC. The sample size for health care workers was determined using the formula for finite population:

$$n = N*X / (X + N - 1),$$

Where,

$$X = Z_{\alpha/2}^2 *p*(1-p) / MOE^2,$$

Where;

N = size of the target population = 90

$Z_{\alpha/2}$ = is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96.

P = Estimated proportion of health workers with knowledge on management of cardiovascular risk factor control in T2DM = 50%

MOE = margin of error = 5%

A Finite Population Correction was applied to the sample size formula.

The computed sample size came to 74. It was assigned to different cadres using proportional allocation to size. The sample size was 6 Medical officers, 66 internal medicine residents and 2 clinical officers.

3.7 Sampling technique

3.7.1 Type 2 DM Patients

Patients with documented file diagnosis of type 2 DM on follow up at the KNH DOPC for at least a period of one year (2019) were studied. Random sampling, via a systematic sampling, approach of all eligible files was carried out. We started with the first file retrieved at the beginning of each data collection day and picked every third file after that until the daily target was met. Selected files were marked to avoid double selection of already sampled files during the course of data collection.

3.7.2 Healthcare Practitioners

Non probability purposive sampling method was used to recruit medical officers, clinical officers and internal medicine residents who were regularly involved in management of T2DM patients.

3.8 Data collection

3.8.1 Retrospective file audits

Permission to access the patient files was sought from the KNH administration and granted. File numbers of patients with a diagnosis of diabetes mellitus were identified from the KNH electronic database using 2020 international codes of diseases (ICD-10 codes E11-).

The records officers then used the files numbers to retrieve them physically from the records office store. Once retrieved in manageable batches of about thirty to forty per day, the principal investigator carefully perused through each file for inclusion into the study.

The files were then carefully studied ,by the PI and two research assistants, to obtain information from the doctor's notes, clinical officer's notes, nutritionist notes, prescriptions, anthropometric measurements, laboratory reports and ECG reports and other radiological reports pertinent to management as stipulated by the data collection tool.

The study tool was adapted, mainly, from the 2018 Kenya National Clinical Guidelines for the management of Diabetes Mellitus (Appendix 5.4) with supplementary input from the European society of Cardiology (ESC) guidelines)/European Association for Study of Diabetes (EASD) consensus report on Management of Cardiovascular Disease in Type 2 DM(73) and American Diabetes Association (ADA) guidelines(71,72) on management of cardiovascular risk in DM. Where there was lack of a common guideline in the above guidelines, we stuck to our local guidelines.

It was a questionnaire in form of a check list with the 5 core sections covering each of the cardiovascular risk factors whose management we sought to audit. Data abstracted from the files included: patient study number, demographic details, duration of type 2 DM, comorbidities and risk stratification. The data was then be subjected to the checklist to ascertain adherence to the above guidelines. The five core sections were derived from the above mentioned guidelines and are the key areas involved in cardiovascular risk management in T2DM. These sections are: management of hypertension, management of glycaemia, management of dyslipidemia, lifestyle modification and use of anti-platelets. Each of these sections was divided into two sub-sections, one dealing with evaluation and the other dealing with treatment. Each of these subsections was populated with questions that required either a Yes/No response or a tick where the response was true.

3.8.2 Quantitative data collection

The questionnaire for the healthcare practitioners was derived from the following practice guidelines: the 2018 Kenya National Clinical Guidelines for the management of Diabetes Mellitus(Appendix 5.4), ESC/EASD consensus report on Management of Cardiovascular Disease in Type 2 DM(73) and ADA guidelines on management of cardiovascular risk in DM(71,72).

Knowledge to be assessed covered six thematic areas namely: risk stratification, management of blood pressure, management of glycaemia, management of dyslipidaemia, lifestyle modification and antiplatelet use in type 2 DM. It contained close ended questions, some of which required a true/false response while others required a single best choice out of the options provided.

The questionnaires were researcher administered, meaning, they were administered by either the principal investigator or the research assistants once informed consent had been sought and obtained from the healthcare practitioners (clinical officers stationed at the DOPC, medical

officers in the medical wards and internal medicine residents). They were delivered to willing participants during breaks and casual meetings within the institution (KNH DOPC and medical wards). Care was taken to ensure that participation in the study did not interfere with service provision.

3.9 Data handling

All the data collected from the study was kept confidential and stored under lock and key by the primary investigator. Any raw data and data-capture forms were also stored safely for scrutiny if need arises later.

3.10 Study variables

3.10.1 File audits:

Independent variables:

i. Age/ D.o.B

ii. Gender

iii. Duration of type 2 DM/ Year of diagnosis

iv. Presence of documented CV risk factors, comorbidities or DM complications

v. Duration of follow up at DOPC

Dependent variables:

These were mostly the guideline directed management (evaluation and treatment) clinical activities/guides.

I. Risk stratification

II. Blood pressure measurement at each visit.

III. Blood pressure treatment targets

IV. ECG done within the past 12 months

V. Microalbuminuria done within the past 12 months

VI. Treatment of hypertension (primarily with RAAS blockade)

VII. HbA1c (done as per recommendation)

VIII. HbA1c treatment targets

IX. Lipid profile (done within the last 12 months)

X. LDL targets as per recommendations

XI. Lipid lowering medication prescribed as per recommendations

XII. Adequate treatment of dyslipidaemia as per recommendations.

XIII. BMI (calculated as per recommendations)

XIV. Waist circumference measurements taken as per recommendations

XV. Smoking cessation advice given/documented

XVI. Advice on alcohol use given/documented

XVII. Dietary modification advice given/documented

XVIII. Advice on physical activity given/documented

XIX. Adequate use of anti-platelets as per recommendations

3.12 Quality assurance

3.12.1 File audits

To help with the data collection, two research assistants were recruited and trained on how to extract the required variables from the files. Furthermore, the principal investigator worked side by side the assistants throughout data collection process.

3.12.2 Quantitative assessment of knowledge of management of cardiovascular risk in type 2 DM.

The questionnaire was reviewed by senior content specialists (endocrinologist and cardiologist) who verified its appropriateness for assessment of management of cardiovascular risk among the corresponding health care cadres.

3.13 Data analysis

3.13.1 File audits

For each of the core risk factors being assessed, the adherence to guidelines was assessed as a percentage of the total clinical activities or guides as prescribed in the guidelines. That is to say, for each section of risk factor management being assessed, the number of responses in the affirmative was divided by the total in that section and presented as percentage of compliance to risk factor management guidelines for that particular risk factor.

Stored data from excel was exported to STATA version 14 for statistical analysis. Study population was described using demographic and clinical characteristics. For continuous variables; appropriate measures of central tendency (mean/median/mode) were reported. Categorical variables were summarized into percentages and proportions. Interventions not documented were considered not done and were documented as such and an arbitrary target score of 100% was used.

3.13.2 Quantitative analysis of healthcare practitioners knowledge

For this section of data analysis, healthcare practitioners' knowledge on cardiovascular risk management was expressed as percentage of correct answers by the respondents. That is, for each question and ultimately each section, the outcome was expressed as the percentage of respondents who chose the correct answer. Blank responses were considered wrong or an assumption that participants most likely were not aware of the right response. For continuous variables; appropriate measures of central tendency (mean/median/mode) and dispersion (Range/IQR/SD) were used in summary statistics. Analysis of level of knowledge among the cadres of clinical staff was performed using a one way analysis of variance.

3.14 Study results dissemination plan

The study results were presented to the Department of Clinical Medicine and Therapeutics. We also offered to present our findings at professional conferences and scholarly journals and if published, we shall endeavor to inform the Ethical Review Committee of the publication.

3.15 Ethical considerations

The study was carried out after presentation and approval by the Department of Clinical Medicine and Therapeutics, University of Nairobi, KNH and the Ethical Review Committee. The data collected from the files was kept under lock and key with access controlled by the principal investigator.

Permission was sought from KNH administration to administer questionnaires to healthcare workers involved in management of patients with T2DM. Permission was also sought from the department of internal medicine to interview internal medicine registrars. Written informed consent was obtained from the healthcare practitioners before their inclusion into the quantitative survey. The collected information remains confidential.

CHAPTER FOUR

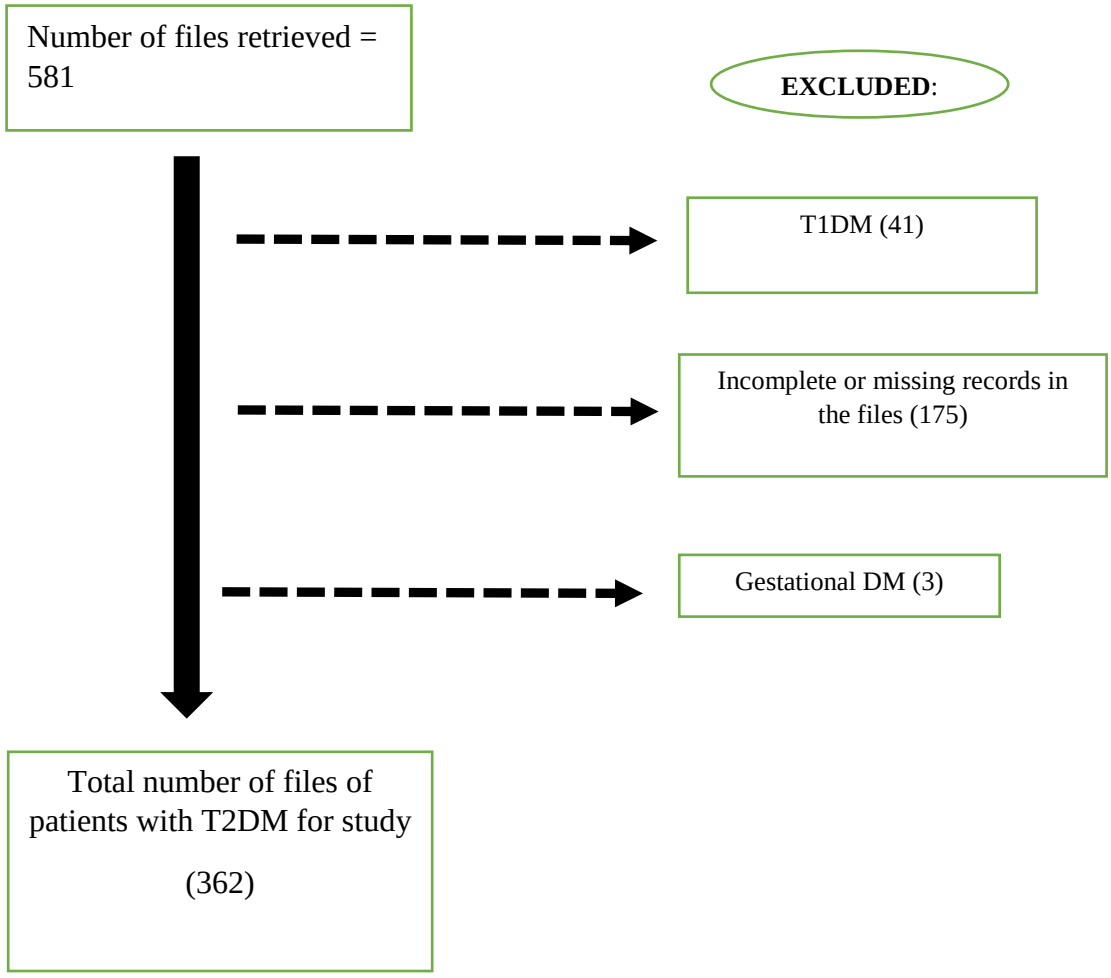
4. Study Results:

4.1 Retrospective audit of files

The study was carried out between 5th January and 12th February 2021 at Kenyatta National Hospital (KNH). Data collection was done at the KNH Diabetes clinic decentralized records department dedicated to files of patients with diabetes mellitus. The files were retrieved in batches of thirty to forty per day and perused for inclusion into the study by the principal investigator assisted by the research assistants.

Five hundred and eighty-one (581) files were scrutinized via a systematic sampling approach, with every third file being comprehensively reviewed for inclusion and exclusion criteria at the beginning of every data collection session up until the sample size was met. Of the initial 581, 41 files were excluded because of the diagnosis of Type 1 DM, three because of the diagnosis of gestational diabetes and finally, one hundred and seventy-five (175) files were excluded because they had incomplete or missing data, leaving 362 files that met the target Sample size. The files that were selected were dully coded. Once the target sample size was met, data collection was stopped. See figure 2.

Figure 2: Flow chart showing recruitment of patient files



4.2 Baseline characteristics

Three hundred and sixty-two (362) files, representing 362 patients, were examined. One hundred and thirteen (31.2%) patients were between the ages of 50 to 59 years. The median age of the patients was 59.0 (IQR 50.0 – 67.0) years, and the youngest age was 30.0 years, while the oldest was 97 years. There were 116 males and 246 females, giving an M: F ratio of approximately 1: 2. The median duration of diabetes was 9 (IQR 4-14) years.

Regarding the number of clinic visits, 173 (47.8%) patients, had had two clinic visits during the period of study, while only 1 (0.3%) patient had five clinic visits. See table 2.

Table 2: Demographic and clinical characteristics of the study participants

	Frequency (n=362)	**Percent (%)**
Age categories in years		
30-39	13	3.6
40-49	69	19.1
50-59	113	31.2
60-69	95	26.2
70-79	55	15.2
80+	17	4.7
Sex		
Male	116	32.0
Female	246	68.0
Duration of diabetes (in years)		
≤10	223	61.6
11-20	105	29.0
21-30	29	8.0
>30	5	1.4
Clinic visits (within the year of study)		
1	95	26.2
2	173	47.8
3	78	21.5
4	15	4.1
5	1	0.3

4.2.1 The documented cardiovascular risk factors among study subjects:

The analysis of the data indicated that out of the 362 patients, 302 (83.4%) presented with at least one or more major cardiovascular risk factors or documented established ASCVD namely: Hypertension (HTN), Dyslipidemia, Cardiovascular disease (CVD), Obesity, and Chronic Kidney disease (CKD). See Table 3.

Table 3: Documented distribution major risk factors plus established ASCVD

	Frequency (n = 362)	**Percent of cases**
Hypertension	295	81.5%
Dyslipidaemia	6	1.7%
Cardiovascular disease	29	8.0%
Obesity	7	1.9%
Chronic kidney disease	15	4.1%

Overall, in terms of numbers of major CV risk factors per patient, 253 (69.9%) of the patients had one, 48 (13.3%) had two, 1 (0.3%) had three, and 60 (16.5%) had none of these, as portrayed in figure 3.

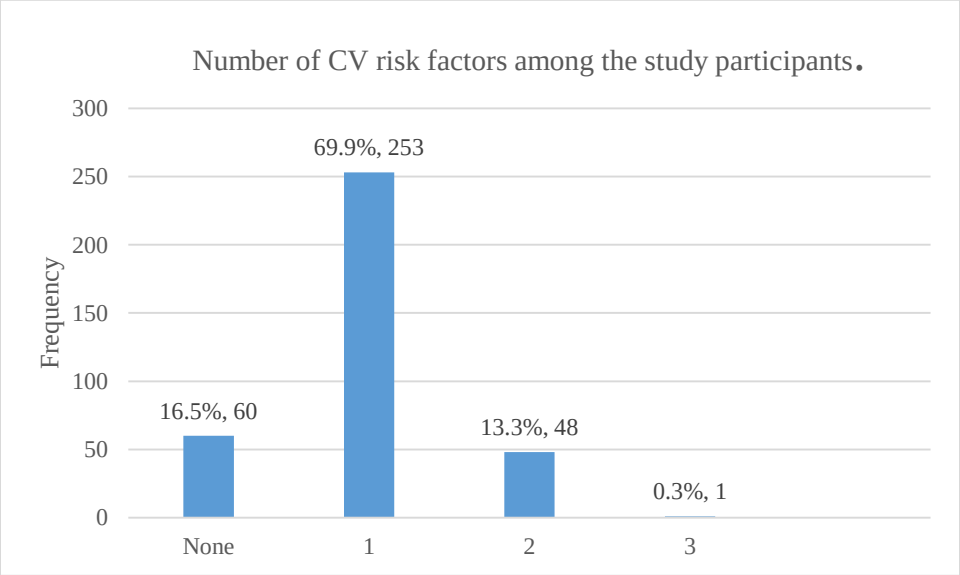


Figure 3: Number of CV risk factors among the study participants.

Of the 362 patients, 29 (8.0%) had documented CVD. Of these, stroke accounted for 16 (55.2%) patients, followed by peripheral vascular disease with 7 (24.1%) patients, heart failure with 4 (13.8%) patients and finally, coronary artery disease accounted for 2 (6.9%) patients.

4.3 Assessment of adequacy of management of cardiovascular risk.

4.3.1 Risk Stratification

There was no evidence of risk-stratification noted in all the 362 patients' records. We, therefore, risk-stratified all the patients as per the records-on-file, based on the current guidelines. Following the risk-stratification: 104 (28.7%) patients met the criteria of very high risk, meaning, DM plus either an established CVD or target organ damage or 3 or major risk factors; 209 (57.7%) were classified as high risk, meaning, a patient with DM duration of equals to or more than 10years without target organ damage, plus any other additional risk factor and finally, 49 (13.5 %) were classified as moderate-risk, meaning, T2DM patient less than 50 years of age with DM duration of less than or equal to 10 years, without any other additional risk factors. See table 4 below.

Table 4: Risk stratification of study subjects

Documented evidence of risk stratification	**Frequency (n=362)**	**Percent (%)**
No	362	100.0
Risk stratification(at enrolment)		
Very high risk	104	28.7
High risk	209	57.7
Moderate risk	49	13.5

4.3.2 Management of hypertension.

Regarding the evaluation of blood pressure (BP) management, 352 (97.2%) patients had their BP taken at every visit. However, documentation of blood pressure treatment targets was done in only three (0.8%) patients.

With regards to evaluation of cardiovascular risk, 69 (19.1%) patients had an ECG requested within the period under study, and 124 (34.3%) patients had microalbuminuria requested.

All of the 295 (81.5%) patients with hypertension on treatment. The majority, 259 (87.8%), of these patients were on a regimen that included RAAS blockade. Of the 295 hypertensive patients, 96 (32.5%) patients had blood pressure recordings within the accepted target guideline range, while 199 (67.5%) patients were not within the target range. In the cohort of patients with poor blood pressure control, only 61 (30.6%) had documentation on the file attempting to probe or explain for possible reasons for blood pressure variations. Such reasons included non-adherence, “white coat hypertension,” or a lack of regular medication supply. Of the patients with poorly controlled hypertension, without documented plausible reasons for the blood pressure variations, 79 (57.2%) had some remedial action to attempt good control. These documented actions included: increase in antihypertensive dosage in 23 (29.1%) patients, the addition of a new class of antihypertensive in 53 (67.1%) patients, and a switch to a different antihypertensive class in 14 (17.7%) patients. Interestingly no action was documented to have been taken to improve control of hypertension in 59 (47.8%) of these patients. See table 5.

Table 5: Management of Blood Pressure of study subjects

Evaluation/Clinical action of interest	**Yes [n(%)]**	**No [n(%)]**
BP was taken at every visit	352 (97.2)	10 (2.8)
Treatment targets specified in the file	3 (0.8)	359 (99.2)
ECG requested within the last year	69 (19.1)	293 (80.9)
Microalbuminuria requested within last year	124 (34.3)	238 (65.7)
Treatment		
Patient primarily on RAAS blockade	259 (87.8)	36 (12.2)
Hypertensive patients' readings each visit within target	96 (32.5)	199 (67.5)
The documented explanation for non-target readings (n=199)	61 (30.6)	138 (69.3)
Documented additional measures were taken for patients with no explanation for non-target readings.(n=138)	79 (57.2)	59 (47.8)
Documented additional measures/clinical actions taken (79 patients), *n (%)*		
Documented increase in drug dosage	23 (29.1)	
Documented addition of new classes of drugs	53 (67.1)	
Documented switching to a different class of drugs	14 (17.7)	
Documented reinforcement of lifestyle modification		
Weight loss advice	2 (2.5)	
Dietary salt restriction	3 (3.8)	
Alcohol restriction	1 (1.3)	
Recommended increased physical activity	3 (3.8)	

4.3.3 Management of glycaemia

Two hundred and sixty-two (72.4%) patients had an HbA1c requested within the previous 12-month-period. On further scrutiny, only half of the patients' files reviewed 181 (50.0%) revealed that the routine HbA1c test was requested as per guidelines, meaning it was either requested every six months if readings were within range or every three months if not within the target range. Two hundred-and-four (56.4%) had no documented or available HbA1c results in their files. Only 158 (43.6%) patients had documented and or available HbA1c results, of which only 55 (34.8%) were within target, while 103 (65.2%) were not. Twenty-seven (7.5%) of all patients

who had HbA1c requested had documentation of the requisite HbA1c targets, and 11 (40.77%) of them had appropriate targets based on current guidelines, while 16 (59.3%) did not. See table 6.

Table 6: Management of Glycaemia of study subjects

Evaluation/ Clinical action	**Yes [n(%)]**	**No [n(%)]**
HbA1c requested within the last 12 months	262 (72.4)	100 (27.4)
Routine HbA1c test requested as per guidelines	181 (50.0)	181 (50.0)
Documentation of HbA1c targets	27 (7.5)	335 (92.5)
Documentation of HbA1c targets based on guidelines (n=27)	11 (40.7)	16 (59.3)
Treatment (158 patients with available HbA1c results)		
Patient HbA1c within the target	55 (34.8)	103 (65.2)
Documented clinical measures taken for documented HbA1c, above target (n=103)		
Documented reinforced lifestyle modification	20 (19.4)	
Documented addition of drug dosage	51 (49.5)	
Documented addition of different class of drugs	21 (20.4)	
Documented initiation of insulin	16 (15.5)	

Of the 103 patients whose HbA1c were not within targets, 61 (59.2%) had one measure in place to remedy the situation, 12 (11.7%) had two measures, 5 (4.9%) had 3, while 2 (1.9%) had four measures respectively. There were 23 (22.3%) who had no measures instituted. The most common measure taken to intensify treatment was addition of the drug dosage.

4.3.4 Documented management of dyslipidaemia

Two hundred and six (56.9%) patients had lipid profiles requested within 12 months. None of the 362 patients (100%) had documented specified targets for LDL control, and subsequently, none had any documented guideline-based targets. Only 97 (26.8%) of the patients had documented lipid profile results, while 265 (73.2%) did not. Of the documented lipid profile results, only 36 (37.1%) were within target levels, while the remaining 61 (62.9%) were not. Of the 61 patients with off-target results, only 19 (31.1%) had a repeat request within 3-6 months as per guidelines (for off-target results), while 42 (68.9%) did not. Statins were used in managing dyslipidemia in

251 (69.3%) patients. However, appropriate doses of the statins as per guidelines was observed and documented in only 34 (9.4 %) patients. See table 7.

Table 7: Management of Dyslipidemia of study subjects

Documented clinical action	**Yes [n(%)]**	**No [n(%)]**
Lipid profile requested within 12 months	206 (56.9)	156 (43.1)
Specified documented targets for LDL control	0(0)	362 (100.0)
Lipid profile requested every 3-6 months for off-target results	19 (31.1)	42 (68.9)
Documented management action		
Statins use for management of dyslipidaemia	251 (69.3)	111 (30.7)
Statin treatment adequate as per guideline	34 (9.4)	328(90.6)

4.3.5 Lifestyle modification

Only seven (1.9%) patients had their BMI calculated on their 3-6 monthly visits, of which only one patient had their BMI classification documented. There was documentation of targeted weight loss in 21 (5.8%) of the 362 patients. See Table 8.

Table 8: Lifestyle modification documented.

Evaluation clinical parameter	**Yes [n(%)]**	**No[n(%)]**
BMI calculated 3-6 monthly visits	7 (1.9)	355 (98.1)
Waist circumference taken 3-6 monthly visits	3 (0.8)	359 (99.2)
Documented clinical action recommended		
Documented advice against smoking	39 (10.8)	323 (89.2)
Documented advice on alcohol avoidance	38 (10.5)	324 (89.5)
Documented evidence on advice on salt intake	46 (12.7)	316 (87.3)
Documented use of individualized diets	45 (12.4)	317 (87.6)
Documented use of tools used in meal planning	45 (12.4)	317 (87.6)
Documented advice on appropriate physical activity	43 (11.9)	319 (88.1)

4.3.6 Documented use of anti-platelets in cardiovascular risk management among study subjects

With regards to the use of anti-platelets for primary prevention in T2DM, 295 (81.5%) patients were stratified as high-risk and were thus eligible for consideration of anti-platelet use for primary prevention barring any contraindications. Of these 295, 53 (14.6%) had an antiplatelet agent used for primary prevention of ASCVD. Eighteen (5.0) patients had documented established ASCVD disease and were thus eligible for secondary prevention. Of these 18, 12 (66.7%) had appropriate use of anti-platelets while 6 (33.3%) did not. The remaining 49 (13.5%) of the 362 patients were stratified as moderate risk and were therefore not eligible for antiplatelet use. See table 9.

Table 9: Antiplatelet agent use in cardiovascular risk management among study subjects

Documented use of anti-platelets for primary prevention of CVD(295 eligible patients)	**Frequency(n)**	**Percent (%)**
Yes	53	14.6
No	242	66.9
N/A (secondary prevention)	18	5.0
N/A (moderate risk)	49	13.5
Recommended anti-platelet for secondary prevention (n=18 patients)		
Yes	12	66.7
No	6	33.3

4.4 Assessment of healthcare practitioners' knowledge on cardiovascular risk factor control among type 2 DM patients.

We assessed the healthcare practitioners' knowledge of cardiovascular risk factor control among T2DM by use of a questionnaire derived from the following practice guidelines: the 2018 Kenya National Clinical Guidelines for the management of Diabetes Mellitus, ESC/EASD consensus report on Management of Cardiovascular Disease in Type 2 DM and ADA guidelines on the management of cardiovascular risk in DM. Knowledge to be assessed covered six thematic areas, namely: risk stratification, management of blood pressure, management of glycaemia, management of dyslipidaemia, lifestyle modification, and antiplatelet use in type 2 DM. It contained close-ended questions, some of which required a true/false response, some had more than one correct response, while others required a single best choice out of the options provided.

Seventy-seven questionnaires were issued to the healthcare practitioners, and 74 of the questionnaires were returned, giving a response rate of 96%. Internal medicine residents comprised 66 respondents, six respondents were Medical officers, and two were Clinical officers stationed at the KNH DOPC.

4.4.1 Demographic Characteristics of Respondents:

The median age of respondents was 31.0 (IQR 29.0 – 33.0) years, and the youngest age was 27.0 years, while the oldest was 55 years. The median years of experience were 6.0 (IQR 5.0 – 7.0) years, and the lowest was 2.0 years, while the highest was 31 years, as portrayed in table 10.

Table 10: Demographic Characteristics of healthcare practitioners participating in the study

Gender	**Frequency (n=74)**	**Percentage (%)**
Male	36	48.6
Female	38	51.4
Age (years)		
<30	20	27.0
30-39	50	67.6
40-49	2	2.7
50 and above	2	2.7
Appointment		
Clinical officer	2	2.7
Medical officer	6	8.1
Part 1 residents	25	33.8
Part 2 residents	41	55.4
Years of experience in clinical work		
Less than 5.0	16	21.6
5.0-10.0	53	71.6
Above 10.0	5	6.8

4.4.2 Risk stratification of cardiovascular risk in type 2 DM.

Concerning cardiovascular risk stratification in type 2 diabetics, the majority (91.9%) of the respondents were aware of an existing risk stratification guideline. However, only 16 (21.6%) were aware of the details of risk stratification as per the available guidelines. Furthermore, only 25 (33.8%) healthcare practitioners were able to correctly identify what constitutes moderate cardiovascular risk, while only 5 (6.8%) could identify what constitutes high cardiovascular risk correctly. See table 11.

Table 11: Knowledge of stratification of cardiovascular risk by study respondents

Knowledge of existing risk stratification	**Frequency (n=74)**	**Percentage (%)**
Yes	68	91.9
No	6	8.1
Knowledge on the grading of risk stratification as per guidelines		
Correct	16	21.6
Wrong	52	70.3
Do not know	6	8.1
Knowledge on what constitutes moderate risk stratification		
Correct	25	33.8
Wrong	39	52.7
Do not know	10	13.5
Knowledge on what constitutes high-risk stratification		
Correct	5	6.8
Wrong	64	86.4
Do not know	5	6.8

4.4.3 Knowledge on management of blood pressure

In terms of management of blood pressure, concerning evaluation; the majority of the respondents (93.2%) had appropriate knowledge about the frequency at which blood pressure readings should routinely be taken, 42 (56.8%) answered correctly with regards to how often a routine ECG should be performed, and 37 (50%) were able to correctly identify how often a routine urine micro-albumin should be done.

Only 6 (8.1%) respondents were correct regarding the different aspects of blood pressure targets to be achieved in T2DM. The rest of the respondents were either unaware or not sure of the documented local guideline targets. Sixty-one (82.4%) respondents were correct regarding the class of drugs recommended for use in reducing cardiovascular risk in T2DM. See table 12.

Table 12: Knowledge of management of blood pressure by study respondents

	Frequency (n=74)	Percentage (%)
Knowledge on how often blood pressure readings should be routinely taken?		
Correct	69	93.2
Wrong	4	5.4
Do not know	1	1.4
Knowledge on how often an ECG should routinely be done?		
Correct	42	56.8
Wrong	31	41.8
Do not know	1	1.4
Knowledge on how often urine microalbumin should routinely be done?		
Correct	37	50.0
Wrong	35	47.3
Do not know	2	2.7
Knowledge of blood pressure targets in Type 2 DM.		
Correct	6	8.1
Wrong	66	89.2
Do not know	2	2.7
Knowledge on drugs used in the management of Hypertension in DM?		
Correct	61	82.4
Wrong	13	17.6

4.4.4 Knowledge on management of glycaemia.

Twenty-eight (37.8%) respondents were correct regarding the guidelines on the recommended frequency of $HbA1_C$ testing while managing diabetes mellitus. The rest of the respondents were either wrong or not sure, with most unaware of the three-monthly routine testing of $HbA1_C$ in cases of poorly controlled patients. Only 6 (8.1%) respondents were correct in identifying all the relevant aspects regarding $HbA1_C$ targets for preventing cardiovascular disease in T2DM. The rest of the respondents were either wrong or not sure, with most unaware of the target of <8% in elderly patients with comorbidities and increased cardiovascular risk factors and also of the local guideline-recommended target of Hba1c of less than 7.0%.

Twenty-two (29.7%) respondents correctly identified all the responses regarding the use of oral hypoglycaemic agents in T2DM patients with and without ASCVD. The rest of the respondents were either wrong or not sure, with most unaware of Metformin plus lifestyle modification as being the first-line management for all T2DM patients unless they had ASCVD. See table 13.

Table 13: Knowledge of management of glycaemia by study respondents

	Frequency (n=74)	**Percentage (%)**
Knowledge on how often HbA1c should routinely be done?		
Correct	28	37.8
Wrong	45	60.8
Do not know	1	1.4
Knowledge on HbA1c targets for preventing cardiovascular disease in type 2 DM?		
Correct	6	8.1
Wrong	66	89.2
Do not know	2	2.7
Knowledge regarding the use of different types of oral antidiabetics in different diabetic populations		
Correct	22	29.7
Wrong	51	68.9
Do not know	1	1.4

4.4.5 Knowledge on management of dyslipidaemia

Forty-four (59.5%) respondents correctly identified how often a routine lipid profile should be done in patients with T2DM. In addition to that, 62 (83.8%) respondents were correctly aware that treatment targets in dyslipidemia were based on a form of risk stratification. However, only 27 (36.5%) and 34 (45.9%) were able to correctly identified this risk stratification's LDL treatment targets for moderate and high cardiovascular risk, respectively. Only 7 (9.5%) of the respondents correctly identified the Kenyan guidelines on the management of dyslipidemia; based on age and risk stratification. Finally, with regards to the correlation of drug dosages with intensity of treatment (moderate or high) for the different statins (Atorvastatin, Rosuvastatin, and Simvastatin), only 8 (10.8%) respondents were able to correctly match the drugs to their dosage based on treatment intensity. See table 14.

Table 14: Knowledge of management of dyslipidaemia by study respondents

	Frequency (n=74)	**Percentage (%)**
Knowledge on how often a routine lipid profile should be done?		
Correct	44	59.5
Wrong	25	33.8
Do not know	5	6.7
Knowledge on whether treatment targets in dyslipidaemia are based on risk stratification		
Correct	62	83.8
Wrong	9	12.2
Do not know	3	4.0
Target LDL in the moderate risk		
Correct	27	36.5
Wrong	29	39.2
Do not know	18	24.3
Target LDL in high risk		
Correct	34	45.9
Wrong	27	36.5
Do not know	13	17.6
Knowledge that statin use and dosage is based on age and risk stratification		
Correct	7	9.5
Wrong Do not know	62 5	83.8 6.7
Knowledge of drug dosages in different statins for different risk stratification		
Correct	8	10.8
Wrong Do not know	52 14	70.3 18.9

4.4.6 Knowledge on lifestyle modification for managing type 2 DM

Nineteen (25.7%) respondents were correct on how often a routine BMI should be done. However, only 12 (16.2%) respondents were fully able to identify all the correct responses with regards to knowledge on the recommended BMI and waist/ hip ratios. Most respondents were unaware of the recommended waist/hip ratio in men and women as being less than 1.0 and 0.85, respectively. Forty-four (59.5%) respondents were correct regarding knowledge of recommended weight loss targets in obese and overweight patients, and only 21 (28.4%) respondents were correct with regards to the recommended exercise types and recommended weekly exercise duration in T2DM. See table 15.

Table 15: Knowledge of management of lifestyle modification by study respondents

	Frequency (n=74)	**Percentage (%)**
Knowledge on how often a routine BMI should be done?		
Correct	19	25.7
Wrong	50	67.6
Do not know	5	6.8
Knowledge on recommended BMI and Waist/hip ratios		
Correct	12	16.2
Wrong	54	73.0
Do not know	8	10.8
Knowledge on recommended weight loss in obese and overweight patients.		
Correct	44	59.5
Wrong	14	18.9
Do not know	16	21.6
Knowledge on recommended exercise in type 2 diabetes mellitus		
Correct	21	28.4
Wrong	47	63.5
Do not know	6	8.1

4.4.7 Knowledge on use of anti-platelets in T2DM

Twenty (27.0%) respondents identified all the correct responses regarding the knowledge on the use of aspirin in T2DM. Most respondents were unaware that aspirin (in the absence of clear contraindication) could be indicated for primary prevention in T2DM patients stratified as having high cardiovascular risk, as shown in portrayed in table 16.

Table 16: Knowledge of antiplatelet use by study respondents

	Frequency (n=74)	Percentage (%)
Knowledge regarding the use of aspirin in type 2 diabetes mellitus patients(T2DM)		
Correct	20	27.0
Wrong	53	71.6
Do not know	1	1.4

4.5 Analysis of level of knowledge among the cadres of clinical staff.

The clinical officers' scores ranged from 32% to 41%, with a mean of 36.4%. The lowest score by the internal medicine residents was 14%, while the highest score was 68%, with a mean score was 39%, and the medical officers' score ranged from 23% to 32%, with a mean of 27%. A one-way ANOVA was conducted to determine if the knowledge of the healthcare workers was different amongst the cadres. The scores' differences were statistically significant between different cadres, p= .046. Further analysis to determine where the differences were, revealed that; the differences were between the medical officers and the internal medicine residents, with a statistically significant difference of p = .036. These results suggest that, compared to a medical officer, being an internal medicine resident is associated with more knowledge on cardiovascular risk management in type 2 DM. See table 17.

Table 17: Comparison of knowledge level (mean scores) between the cadres.

Cadre	Frequency	Mean	SD	95% CI for the Mean
Clinical officers	2	36.4	6.4	-21.4 – 94.1
Medical officers	6	27.3	4.1	23.0 – 31.5
internal medicine residents	66	38.6	10.9	35.9 – 41.3

4.6 Discussion

We set out to assess the adequacy of cardiovascular risk factor management in T2DM and healthcare practitioners' knowledge of the same, at the KNH. In the audit of T2DM files, there was a female preponderance which was similar to findings from a recent local study by Kimando et al. done at the Nyeri County Referral Hospital in 2015, with a similar female predominance (65.5%)(8). We suspect that this could be explained by a higher health-seeking behavior in women compared to men, since available local literature doesn't show a significant gender difference in diabetes prevalence(10). Furthermore, estimated prevalence of diabetes in women worldwide is slightly lower than in men(1). The mean age and average duration of follow up were both comparable to the previously mentioned, recent local literature by Kimando et al(8). The average number of clinic visits was 2. A majority of our patients had 2 or less clinic visits per year which was much lower compared to the local study by Kimando et al. that reported majority (86%) of their patients having 3-4 clinic visits a year(8). In comparison, this could suggest reduced access to care for our patients and perhaps explain some of the challenges with achieving adequate cardiovascular risk factor control, especially with respect to hitting treatment targets. However, it is crucial to put things in to perspective. KNH DOPC, being part of a referral hospital, inevitably serves a much larger population. The duration of clinic visits might be affected by a large number of patients on the waiting list due to the sheer numbers that require to be seen vis-à-vis how many patients can comfortably be seen during each clinic visit, without compromising quality of care accorded. To be clear, there isn't a defined standard number of visits recommended by the guidelines, they however recommend that number of visits should be dependent on whether patients' various treatment targets are being met.

Approximately half of the patients had one or more major risk factors associated with increased cardiovascular risk and subsequent cardiovascular disease, and of these, hypertension was the most prevalent. This was comparable to recent local data from Kimando et al. (8) at 49.4% and to global estimates at 50% as well(40). The prevalence of documented cardiovascular disease in our patients was much lower than global estimates of 32.2% reported by Einarson et al(11). We suspect that this could be due to the diagnostic handicaps associated with our low income setting. Most of the patients seen in LMIC settings have challenges affording certain diagnostic investigations due to the available cost-sharing models, poor uptake of health-insurance among other socio-economic factors(79).

For each core sections covering each of the cardiovascular risk factors whose management we sought to audit, we found a mixed picture in terms of overall adherence to guideline directed management of cardiovascular risk. There was an overall poor performance, especially with regards to the evaluation aspect. Perhaps, this could be due to lack of awareness of guideline directed evaluation parameters and their and their recommended timelines. A point that has been echoed by audits done in South Africa(80,81).

It was quite telling that of all the patients' files audited, none had any form of cardiovascular risk stratification, yet a majority of the patients fell in the category of high-risk to very high risk. This failure could be a reflection of healthcare practitioner lack of knowledge on cardiovascular risk stratification in T2DM, a point echoed by the quantitative survey which demonstrated a clear lack of sufficient knowledge on the existing risk stratifications strategies and what constitutes the different levels of risk strata in type 2 diabetics, in whom the lowest form of risk stratification is moderate risk. Literature has shown that, risk stratification among T2DM patients not only improves accuracy in prediction of subclinical cardiovascular events such a silent ischemia, but also prevents future cardiovascular events(82). Therefore, managing T2DM patients without stratifying their risk leads to sub-optimal management concerning adequate evaluation, adequate treatment targets, the correct choice of drugs, and adequate dosing of those drugs, as demonstrated by most of our findings. Further studies may be necessary to determine the barriers to adequate risk stratification among our patients on follow-up. Little data is available on uptake of cardiovascular risk stratification of T2DM patients both locally and globally, making it difficult to draw comparisons or make conclusions as to whether this is purely a local problem, or it is something pervasive.

Controlling hypertension is vital to minimizing cardiovascular risk in T2DM patients. Regarding the management of hypertension, specifically, the evaluation aspect, measurement of blood pressure at every visit was the best performed measure with almost all patients having it done, reflecting a well-established routine that accompanies every patient's clinic visit. The good performance in blood pressure monitoring may well be since it is a routine nursing practice to take blood pressure as a prerequisite in triaging patients. This was comparable to data from an audit on hypertension in diabetics done in a similar LMIC setting(83). Well over half the patients sampled were hypertensive. This prevalence was comparable to data from a South African clinical audit (89.1%) but much higher than a recent local study (49.6%) and overall global

estimates that simply report rates of more than 50%(8,42,80). With regards to additional recommended evaluation for cardiovascular risk, performance of recommended routine investigations such as an ECG and urine micro-albumin were poorly performed with recommended performance in almost less than a third of patients, for both investigations. This was much lower than results from a similar audit on management of hypertension in diabetics in primary healthcare clinics in Jamaica, which reported much higher performance of recommended routine ECG (76%)(83). Furthermore less than one percent of the patients had documented treatment targets to guide management.

Positively, majority of the patients were on a regimen primarily composed of RAAS blockade. These figures were similar to data from a local study (69%) and also to similar LMIC audits in Jamaica (86.2%) and South Africa (80.4%) with regards to use of RAAS blockade in hypertensives with type 2 DM(8,80,83). This signals widespread knowledge of benefits of RAAS blockade in DM, which has been shown to improve cardiovascular outcomes(84). Over half of the patients had off-target readings, with only about a third of these with documented attempts to find possible reasons for the abnormal readings. These off-target readings are not unique to our setting as similarly poor rates of blood pressure control have been reported in literature from both LMIC and HIC settings with rates ranging between 25.1%-56%(80,85,86). Off-target readings prompted a response from healthcare practitioners in slightly over half of patients with poorly controlled hypertension, with the most common documented corrective measure taken to intensify treatment, being addition of a new class of drugs. Meanwhile, no action was documented as having been taken to improve control of hypertension in the remaining, slightly under half of, patients in the poorly controlled cohort. These findings are concerning, given the demonstrable knowledge provided by studies such as the U.K. Prospective Diabetes Study (UKPDS) and Hypertension Optimal Treatment trial, that showed tight control of blood pressure to be associated with significant reductions in the risk of stroke, macrovascular complications, and diabetes-related mortality(87,88).

With regards to healthcare practitioners' knowledge on management of blood pressure, the performance was slightly better. More than half of the respondents demonstrated sufficient knowledge on aspects of routine evaluation of blood pressure and its management, with respect to the class of drugs recommended for use in reducing cardiovascular risk in T2DM. However, very few respondents had sufficient knowledge on the different aspects of blood pressure targets

to be achieved in T2DM with majority either unaware or not sure of the documented local guideline targets, which was reflective of file audit findings.

Well over half of the patients had an HbA1c requested within the previous 12-month-period which was encouraging. However, only half had the routine HbA1c test requested as per guidelines. This was much lower when compared to both the 79.7% reported in a Malaysian T2DM clinical care audit(85) and to the 85.1% reported closer home, in study done in Webuye, in western Kenya(89). Documentation of the requisite HbA1c targets was dismal with only slightly over a third of the documented targets being in line with existing guidelines. This could reflect a lack of clear knowledge of local guidelines on routine testing and presence of individualized targets according to duration of DM, comorbidities and age, and the importance of tailor-making each patient's management plan. These findings were echoed by the quantitative survey of healthcare practitioners' knowledge which demonstrated insufficient knowledge on different aspects of glycaemic control, with less than half of the respondents fully knowledgeable on the current guidelines with respect to routine HbA1c testing, guideline directed targets and all relevant aspects of the use of oral hypoglycaemic agents in T2DM patients, with and without ASCVD. Knowledge of these individualized HbA1c targets is crucial to appropriate control of glycaemia, especially in avoiding the negative effects of very stringent control in the different populations of T2DM patients, more so the elderly. Of the available HbA1c results within the files, the figures showed a predominance of poor glycaemic control with more than half of patients' values being outside of guideline targets. This could be as a result of the aforementioned inadequate routine testing and lack of target-driven management. This observation is comparable to literature from audits in LMIC, with similar rates of poor glycaemic control ranging from 15.5%-39.5%(8,80,83). In comparison, data from a meta-analysis from HMIC reported slightly better glycaemic control with rates ranging from 44.5%-60% (depending on HbA1c targets used in different countries' guidelines)(90). It was slightly encouraging that in more than half of our patients, out-of-target readings prompted the healthcare practitioners to remedy the situation by intensification of treatment. The majority were documented to institute at least one additional measure, the most common being addition of the patient's drug dosage, thus highlighting the benefit of using evolving patient data to guide management.

The overall performance on management of dyslipidaemia was unsatisfactory. Slightly over half of the patients had routine lipid profiles requested within 12 months, however, this was still

lower than the 65% reported in literature from a similar audit in LMICs(83) and much lower than figures from a Malaysian audit that reported annual testing for fasting lipid profile at 99.6%(85). None of the patients had documented LDL targets and subsequently, none had any documented guideline-based targets. Effectively, these patients were being managed without a clear goal upon which evolving data could be used to direct their management. This pales in comparison to HIC data from the GUIDANCE study, encompassing eight European countries, where majority of their patients were treated based on LDL targets(90). Of the documented lipid profile results, there was a predominance of dyslipidaemia which was comparable to data found in literature from predominantly Low and Middle-Income Countries(8,80,83,89). It is also of note that findings of actual number of patients with dyslipidaemia based on available lipid profile results was much higher than the documented file diagnoses of dyslipidaemia, pointing to probable under-diagnosis with likelihood of a much higher prevalence of dyslipidaemia in our diabetic population than previously stated. In most of our patients, an abnormal or off-target result didn't prompt the healthcare practitioner to request a repeat test within 3-6 months as stipulated by local guidelines. Statins were used for managing dyslipidemia in majority of the patients, this was much higher than findings from recent local studies in rural parts of Kenya which reported significant under-usage of statins(8,89). However, on further scrutiny, appropriate use of statins (with regards to drug dosing in the management of dyslipidemia as per guidelines) was observed in a minority of the patients. This discrepancy between knowledge on need to prescribe statins versus accurate dosing of the statins is common practice, as shown by Teeling et al.(91). Furthermore, these findings demonstrate a significant lack of awareness of guideline-directed LDL targets, routine testing and optimal use of statins based on risk stratification and are somewhat reflective of the findings from the quantitative survey. More than half of the respondents had sufficient knowledge on routine lipid profile testing, and that treatment targets in dyslipidemia were based on risk stratification but, there was insufficient knowledge on what correctly represents LDL treatment targets for the different risk stratifications. Furthermore, there was insufficient knowledge on local guideline-directed management of dyslipidemia based on age and risk stratification and majority of the respondents were also unable to correctly match the drugs to their dosage based on treatment intensity, both echoing the results from the file audits. These two aspects of management of dyslipidaemia had dismal correct response rates, both averaging approximately only 10%. This undoubtedly results in sub-optimal management of dyslipidaemia in type 2 diabetics, in whom it is the major risk

factor for macrovascular complications. An elevated LDL-C is the major culprit in terms of risk for CVD ,therefore, its rigorous management should be a primary goal of management in CVD prevention(41,59,60).

The section on lifestyle modification had by far the greatest challenges in terms of the audit process due to significant gaps in documentation. Admittedly, numerous aspects of this section tend to be verbalized to the patient during clinic visits without subsequent documentation of the same. There was a disconnect between the two sets of healthcare practitioners caring for the patients (primary clinician and nutritionist) due to the structuring of patient referral system to the nutritionist at the DOPC, resulting in patients been seen by the two cadres in an uncoordinated fashion. Similar struggles occasioned by poor interlinkage of documentation due to a largely paper-based system have been reported elsewhere in SSA(81). Most of the lifestyle education is based on group teachings following a structured booklet (handed out then) covering most of the relevant aspects, which is similar to what happens in primary healthcare facilities offering diabetic care in South Africa(81). This system leads to absence of the nutritionist's notes in the main file used during routine clinic visits. Therefore, the primary clinician is unable to fully know the level of education on lifestyle modification that the patient has received. This was reflected in the findings with poor documentation of: BMI calculation on their 3-6 monthly visits, BMI classification, weight loss targets and finally, lifestyle modification advice. These findings were much less than those from other Low and Middle-Income Countries(80,85). The lifestyle modification section of the quantitative survey had a similar trend and uncovered gaps in knowledge amongst respondents with regards to, how often BMI evaluation should be done and on the recommended BMI and waist/ hip ratios in both men and women, both receiving less than 30% correct response rates. Slightly over half of the respondents were knowledgeable on recommended weight loss targets in obese and overweight patients while only less than a third were correct with regards to the recommended exercise types and recommended weekly exercise duration in T2DM.

Regarding the use of anti-platelets for primary prevention, a minority of the two hundred and ninety-five high-risk patients had an antiplatelet agent used as primary prevention. These figures were much lower than those reported in a similar setting in Jamaica (51.5%)(83) and those reported in an American study (54%)(92). This was echoed by findings from the quantitative survey which showed that majority of the respondents were unaware that aspirin, in the absence

of clear contraindications and when benefit outweighs the risk, could be indicated for primary prevention in T2DM patients stratified as having high cardiovascular risk as it results in reduction in CV events(93). To this end, we found less than 1% of patients in whom aspirin was stopped due to documented increased risk of gastrointestinal bleeding. Finally, of the 18 patients in whom secondary prevention of ASCVD was indicated, majority had appropriate use of anti-platelets as stipulated by the guidelines.

All in all, the audit revealed sub-optimal management of T2DM patients with very low rates of targets attained in all areas. Our performance was somewhat similar to that revealed in a similar audit of a diabetic clinic at a tertiary facility in South Africa(80). With regards to healthcare practitioners' knowledge of cardiovascular risk factor control in patients with type 2 DM, we found overall low level scores among all the cadres involved. Internal medicine residents performed fairly better, followed by the clinical officers and finally, the medical officers had the least performance. These findings on healthcare practitioners' knowledge were somewhat comparable to other studies from LMIC assessing fidelity to guideline directed management in diabetes, with most reporting significant knowledge gaps(94–97).

Knowledge and guidelines on management of cardiovascular risk in T2DM need to be widely disseminated regularly amongst all cadres of healthcare, particularly those involved in management of type 2 diabetics. This is unlikely to be the case in our setup, as shown by the findings of this study. Dissemination of this knowledge would help improve management of cardiovascular risk factors resulting in their adequate control and the subsequent ripple effect of a reduction in cardiovascular disease. We believe that further research is required, including qualitative studies, to understand barriers to achieving adequate management of cardiovascular risk factors in our setting.

4.7 Conclusion

There was an overall low and variable performance across most aspects of cardiovascular risk management as uncovered by both arms of the audit. Although Internal medicine registrars and the clinical officers stationed at the DOPC had slightly more knowledge on various aspects of management of cardiovascular risk in T2DM as compared to the medical officers, their level of knowledge was still way below average and lacking in many aspects. We concluded that cardiovascular risk factor management was inadequate, likely due insufficient knowledge on current guideline-directed management.

4.8 Strengths of the study

The study has highlighted deficiencies in management of cardiovascular risk in type 2 diabetics, both in terms of knowledge and practice most of which can be systematically addressed. KNH is a learning institution and most of the participants are available for updates on guideline directed management of cardiovascular risk among type 2 diabetics.

4.9 Limitations

This being a study with a retrospective component, we encountered missing files, poor documentation and incomplete information as a major limitation; however, the retrospective design was appropriate as it negates the possibility of influencing the care given.

4.10 Recommendations

1. Organization of regular education fora on management of cardiovascular risk in type 2 diabetes mellitus, whereby guidelines on the same can be disseminated to the entire team that is involved in the care type 2 diabetics, to improve awareness and adherence to guidelines, especially with respect to management of cardiovascular risk in T2DM.
2. Develop a Cardiovascular Risk management checklist or assessment form with all the relevant performance indicators and their timelines that can be attached to each file of diabetic patients on follow up at the DOPC, this will help keep track of management of cardiovascular risk as well as standardize it. This form can be modelled on the existing foot assessment form that already exists in most of the patients' files
3. Further research is required, including qualitative studies, to understand barriers to achieving adequate cardiovascular risk factor management in our setting.
4. Schedule regular audits with clear performance indicators as this will improve adherence to the stipulated guidelines
5. Institute addition of other anthropometric measurements such as weight and height, in addition to BP and RBS measurements, during each visit. This will go a long way in assessment of BMI.

4.11 References.

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Chapter 5

5 Appendices

5.1 Retrospective audit study tool.

Audit tool design

Patient data.

1. Study number …….
2. Gender Male ☐ Female ☐
3. Age (years) / Date of birth ……
4. Duration of Type 2 Diabetes/ Year of diagnosis …….
5. Number of clinic visits (within the last year) ……...……..
6. Any History of Comorbidities? Yes ☐ No ☐
   a. If the answer to 6 is yes, tick appropriately
      I. Hypertension ☐
      II. Dyslipidemia ☐
      III. Cardiovascular disease (for example: Stroke/ Heart Failure/Peripheral vascular disease) ☐
      IV. Obesity ☐
      V. Chronic kidney disease ☐
      VI. Other ……
7. Written evidence of risk stratification? Yes ☐ No ☐
8. If the answer to 7 is no, then stratify risk.
   a. High risk ☐
   b. Moderate risk ☐

Measurements/ Parameters recorded

	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**
Blood Pressure				
Blood Glucose				
Hba1c				
Weight				
Height				
Waist Circumference				
BMI				
Albuminuria				
ECG				
Lipid profile: Total Cholesterol LDL Cholesterol HDL Cholesterol Triglycerides				
Creatinine				
DRUGS:				

MANAGEMENT OF BLOOD PRESSURE

Evaluation

9. Is the blood pressure taken at every visit? Yes ☐ No ☐
10. Are there any treatment targets specified in the file? Yes ☐ No ☐
11. Has any ECG been requested within the last year? Yes ☐ No ☐

12. Has a microalbuminuria been requested within the last year?

Yes ☐ No ☐

A. Treatment

13. Is the patient primarily on RAAS blockade? (Either ACE-inhibitor or ARB) or on a combination that has RAAS blockade?

Yes ☐ No ☐

14. Are all of the patient's readings over the past year within target?

Yes ☐ No ☐

15. If the answer to 14 is No, is there a documented explanation for any variations, such as: non-compliance, white coat hypertension, running out of medication and any other explanation?

Yes ☐ No ☐

16. If the answer to 15 is No, have any additional measures been taken by the practitioner to address the situation?

Yes ☐ No ☐

17. What measures, tick appropriately?

a) Addition of new class of drugs ☐

b) Switching to different class of drugs ☐

c) Documented reinforcement of lifestyle modification

I. weight loss advice ☐

II. dietary salt restriction ☐

III. Alcohol restriction ☐

IV. Recommended increased physical activity ☐

MANAGEMENT OF GLYCAEMIA

A. Evaluation

18. Has an Hba1c been requested within the last 12 months? Yes ☐ No ☐

19. Are there documented Hba1c targets? Yes ☐ No ☐

20. If answer to 18 is yes, are targets based on the guidelines?

Meaning:

a. Target is 6.5% – <7.0% for general population

b. Target is <8.0% for Elderly high Cardiovascular risk

Yes ☐ No ☐

21. Is routine Hba1c testing being requested as per guideline recommendations?

Meaning:

a) Is Hba1c being requested 6 monthly if at target?

b) Is Hba1c being requested 3 monthly if not at target?

Yes ☐ No ☐

B. Treatment

22. Patient Hba1c within target? Yes ☐ No ☐

a. If answer to 21 is No, What measures have been taken by the practitioner to address the situation? Tick appropriately

i. Reinforced lifestyle modification ☐

ii. Addition of drug dosage ☐

iii. Addition of different class of drugs ☐

iv. Initiation of insulin ☐

MANAGEMENT OF DYSLIPIDEMIA

A. Evaluation

23. Has a routine lipid profile been requested within the last 12 months? Yes ☐ No ☐

24. Are there specified documented targets for LDL control based on risk? Yes ☐ No ☐

25. If the answer to 23 is yes, are targets based on the guidelines?

    Meaning:

    a. Target is <2.6 mmol/l for moderate CV risk.

    b. Target is <1.8mmol/l for high CV risk.

    Yes ☐ No ☐

26. Has a lipid profile been requested every 3-6 months if results are abnormal or not on target? Yes ☐ No ☐

B. Management

27. Are statins (HMG-COA reductase inhibitors) being used as the 1st line drug of choice in management of dyslipidaemia in these patients?

    Yes ☐ No ☐

28. Is statin treatment adequate as per guidelines directed management of CV risk?

    Meaning;

    a. High risk patients (DM duration > 10yrs without target organ damage, plus any other risk factor) are on high intensity statins+ lifestyle modification

    b. Patients with moderate risk that is:

        i. <40 years with history of ASCVD,

        ii. Within 40 – 75 years,

        iii. > 75 years without ASCVD,

        Are on moderate intensity statin + lifestyle modification?

        Yes ☐ No ☐

LIFESTYLE MODIFICATION

A. Evaluation

29. Is the BMI calculated at 3-6 monthly visits? Yes ☐ No ☐

    a. If 1 is true, is BMI classified? (Underweight\Normal\Overweight\Obese)

    Yes ☐ No ☐

30. Is waist circumference taken at 3-6 monthly visits? Yes ☐ No ☐

B. Treatment

31. Has smoking cessation been advised (for smokers) or smoking avoidance been advised (for non-smokers)? Yes ☐ No ☐

32. Has alcohol avoidance been advised (for both alcohol and non-alcohol takers?)

    Yes ☐ No ☐

33. Is there documented dietary modification?

    a. Documented Advice on salt intake? Yes ☐ No ☐

    b. Individualized diets or recommended portions of food groups?

    Yes ☐ No ☐

    c. Use of tools used in meal planning for example Plate model, Handy portion guide etc. Yes ☐ No ☐

34. Are there documented weight loss targets or strategies in obese and overweight individuals? Yes ☐ No ☐

35. Is there documented appropriate advice on physical activity (moderate to vigorous physical activity, combining aerobic and resistance exercise for more than 150min a week)?

    Yes ☐ No ☐

Use of Anti-platelets in cardiovascular risk management.

36. Is there use of an anti-platelet agent as primary prevention in patients with high cardiovascular risk?

    Yes ☐ No ☐

37. If the answer to 35 is yes, is the use of an anti-platelet agent as primary prevention as per the guidelines?

    Yes ☐ No ☐

38. Is there recommended use of anti-platelets for secondary prevention in established atherosclerotic cardiovascular disease? Yes ☐ No ☐

5.2 Study Proforma

To be filled by Healthcare practitioners (Medical officers, Internal medicine Registrars and Clinical officers)

Date of assessment _____

Age (yrs.): ☐

Sex: Male ☐ Female ☐

Appointment:

Clinical Officer ☐

Medical officer ☐

Senior house officer Part 1 ☐ Part 2A ☐ Part 2B ☐

Years of clinical experience: ☐

Study number: ☐

5.3 Quantitative assessment study tool

Questionnaire to be answered by healthcare practitioners

A. Risk stratification.

Respond appropriately with an X or tick.

1. Do you know of any risk stratification used to assess cardiovascular risk in type 2 Diabetes mellitus (DM)?

   Yes ☐ No ☐

2. If the answer to 1 is yes, please tick the appropriate choice that illustrates the risk stratification.
   a) Low risk, medium risk , high risk
   b) Moderate risk, high risk
   c) Mild risk, moderate risk, high risk
   d) None of the above

3. Which of the following corresponds to moderate risk stratification?
   a) DM duration equal to or more than 10 years without target organ damage.
   b) Type 2 DM less than 50 years with DM duration less than 10 years, without other risk factors
   c) Type 2 DM plus three or more cardiovascular risk factors.
   d) All of the above.

4. Which of the following corresponds to high risk stratification?
   a) DM duration equal to or more than 10 years without target organ damage
   b) Type 2 DM at 50 years with DM duration less than 10 years without target organ damage plus any other risk factors.
   c) DM with target organ damage
   d) None of the above

B. Management of blood pressure

5. How often should blood pressure readings routinely be taken?
    a) At every visit
    b) 3 monthly
    c) 6 monthly
    d) Yearly
6. How often should an ECG routinely be done?
    a) At every visit
    b) 3 monthly
    c) 6 monthly
    d) Yearly/12 monthly
7. How often should urine micro albumin routinely be done?
    a) At every visit
    b) 3 monthly
    c) 6 monthly
    d) Yearly/12 monthly
8. Which of the following are true regarding Blood pressure targets in Type 2 DM. (More than one correct response, only tick those that are true)
    a) Recommended 2018 Kenya National Clinical Guidelines target is <140/80.
    b) Patients at higher risk of cardiovascular disease or with documented microalbuminuria can be targeted to below or equal to 120/80 if tolerated.
    c) Patients at higher risk of cardiovascular disease or with documented microalbuminuria can be targeted to below or equal to 130/80 if tolerated.
    d) Patients at higher risk of cardiovascular disease can be targeted to below or equal to 130/75 if the drugs side effects are tolerated.
    e) Patients 80 years and older without cardiovascular disease have a less stringent target of <150/90.

9. Which of the following is true regarding management of Hypertension in DM?
    a) Calcium channel blockers + Thiazide/ thiazide like diuretics are the recommended first-line particularly in the presence of microalbuminuria, proteinuria or left ventricular hypertrophy.
    b) RAAS blockers (ACE-I/ARB) or RAAS blockers are the recommended first-line or particularly in the presence of microalbuminuria, proteinuria or left ventricular hypertrophy.
    c) Beta blockers are the recommended first-line particularly in the presence of microalbuminuria, proteinuria or left ventricular hypertrophy.
    d) Lifestyle modification should be encouraged in addition to medication.
    e) A and D
    f) B and D

C. Management of glycaemia.

(For the questions in this section, there are more than one correct responses, tick only the correct responses)

10. How often should Hba1c routinely be done?
    a) Annually
    b) 6 monthly if at target
    c) 3 monthly if at target
    d) 6 monthly if not at target
    e) 3 monthly if not at target
    f) At every visit.
11. Which one the following are true regarding Hba1c targets for preventing cardiovascular disease in type 2 DM?
    a) Recommended target is less than 7.0%.
    b) Recommended target is less than 6.0%.
    c) Possible to target an Hba1c of less than 6.5% on a personalized basis if achievable without hypoglycaemia.
    d) Hba1c targets are individualised according to duration of DM, comorbidities and age.
    e) Target of <8% in elderly patients with comorbidities and increased cardiovascular risk factors.
12. Regarding use of oral antidiabetics in type 2 diabetes mellitus.
    a) Metformin plus lifestyle modification is the first line for all type 2 diabetes mellitus patients.
    b) Metformin plus lifestyle modification is the first line for patients with atherosclerotic cardiovascular disease or patients at high/very high cardiovascular risk.
    c) An SGLT2 inhibitor or GLP-1 Receptor agonist plus lifestyle modification is first line for all patients.
    d) An SGLT2 inhibitor or GLP-1 Receptor agonist plus lifestyle modification is first line for patients with atherosclerotic cardiovascular disease or patients at high/very high cardiovascular risk.
    e) Thiazolidinediones are recommended in patients with heart failure.

D. Management of dyslipidaemia

(Pick out the true choice in the following questions)

13. How often should a routine lipid profile be done?

a) 3 monthly
b) 6 monthly
c) Annually
d) None of the above

14. Treatment targets in dyslipidaemia are based on risk stratification?

a) True
b) False
c) Sometimes
d) None of the above

15. What is the target LDL in moderate risk?

a) 2.6mmol/l
b) 1.8mmol/l
c) 1.4mmol/l
d) 1.6 mmol/l

16. What is the target LDL in high risk?

a) 1.8mmol/l
b) 2.6mmol/l
c) 1.2mmol/l
d) 1.4mmol/l

17. For the following, tick either true/false.

a) Statins are the first line treatment of lipids in DM ☐
b) Patients of all ages with atherosclerotic cardiovascular disease (ASCVD) require high intensity statins. ☐
c) Diabetic patients aged 40-75 require moderate intensity statin plus lifestyle modification. ☐
d) Diabetic patients aged 40-75 require high intensity statin plus lifestyle modification. ☐

e) Diabetic patients aged > 75 without ASCVDD require no statin, only lifestyle modification. ☐

f) Diabetic patients < 40 years with ASCVD risk factors require high intensity statin plus lifestyle modification. ☐

18. For the following drug dosages, tick either true/false.

a) Atovastatin 10-20mg is moderate intensity. ☐
b) Rosuvastatin 5-10mg is considered high intensity. ☐
c) Atovastatin 40mg is considered high intensity. ☐
d) Simvastatin 20-40mg is considered high intensity. ☐
e) Rosuvastatin 10mg is considered moderate intensity. ☐

E. Lifestyle modification

19. How often should a BMI routinely be done?

a) Annually
b) At every visit
c) Three to six monthly
d) None of the above

20. Which of the following are true?

a) Recommended BMI is less than 27 and more than 19
b) Recommended waist/hip ratio in men is less than 0.85
c) Recommended waist/hip ratio in women is less than 0.85
d) Recommended BMI is less than 25 and more than 18.
e) Recommended waist/hip ratio in men is less than 1.0
f) Recommended waist/hip ratio in women is less than 1.0

21. Regarding recommended weight loss in obese and overweight patients.
    a) At least <5% weight loss should be prescribed for those ready to achieve weight loss.
    b) At least 5%-10% weight loss should be prescribed for those ready to achieve weight loss.
    c) At least >25% weight loss should be prescribed for those ready to achieve weight loss.
    d) At least <20% weight loss should be prescribed for those ready to achieve weight loss.
    e) None of the above.
22. Regarding recommended exercise in type 2 diabetes mellitus, which one is true?
    a) Mild to moderate physical activity consisting of aerobic exercise for more than or equal to 150min a week is adequate.
    b) Moderate to vigorous physical activity consisting of resistance exercise for more than or equal to 100min a week is adequate.
    c) Moderate to vigorous physical activity consisting of aerobic and resistance exercise for more than or equal to 150 min a week is adequate.
    d) Moderate to vigorous physical activity consisting of aerobic and resistance exercise for more than or equal to 250 min a week is adequate.
    e) None of the above.

F. Antiplatelet use.

23. Which of the following are true regarding the use of aspirin in type 2 diabetes mellitus patients(T2DM).(tick only on the true responses)
    a) Aspirin is indicated for primary prevention in all patients with T2DM.
    b) Aspirin as primary prevention is indicated in T2DM stratified as high cardiovascular risk in the absence of clear contraindications.
    c) Aspirin is indicated for secondary prevention in patients with atherosclerotic cardiovascular disease.
    d) None of the above.

5.4 Various targets as per available guidelines

5.4.1 Kenya National Clinical Guidelines for Management of Diabetes Mellitus.

Copied from Kenya national clinical guidelines for management of diabetes mellitus 2018.

Other risk factors, asymptomatic organ damage or disease	Blood pressure (mmHg)			
	Pre-HTN SBP 130–139 or DBP 85–89	Stage 1 HTN SBP 140–159 or DBP 90–99	Stage 2 HTN SBP 160–179 or DBP 100–109	Stage 3 HTN SBP ≥180 or DBP ≥110
No other RF		Low risk	Moderate risk	High risk
1–2 RF	Low risk	Moderate risk	Moderate to high risk	High risk
≥3 RF	Low to moderate risk	Moderate to high risk	High risk	High risk
OD, CKD stage 3 or diabetes	Moderate to high risk	High risk	High risk	High to very high risk
Symptomatic CVD, CKD stage ≥ 4 or diabetes with OD/RFs	Very high risk	Very high risk	Very high risk	Very high risk

BP = blood pressure; CKD = chronic kidney disease; CV = cardiovascular; CVD = cardiovascular disease; DBP = diastolic blood pressure; HT = hypertension; OD = organ damage; RF = risk factor; SBP = systolic blood pressure.

Risk factors (RF) include: smoking, age (men >55 years, women <65 years), dyslipidaemia, male sex, obesity, central adiposity, family history of premature CVD (men <55 years, women <65 years) and impaired glucose tolerance)

Figure 4: Stratification of total CV risk based on SBP and DBP and prevalence of Risk factors, asymptomatic OD, diabetes, CKD stage or symptomatic CVD

Adapted from the ESH/ESC Guidelines for the management of arterial hypertension, 2013

Table 18: CVD risk factors and targets for type 2 diabetes

Traditional CVD risk factors	Targets
Cigarette smoking	Cessation
Dyslipidaemia	
– Total cholesterol	<4.5 mmol/L
– LDL cholesterol	<1.8 mmol/L
– HDL cholesterol	> 1.0 mmol/L (men) >1.2 mmol/L (women)
– Triglycerides	<1.7 mmol/L
Obesity	
– Waist circumference	<94 cm (men); <90 cm (men of South Asian descent) <80 cm (women)
– Body mass index	<25 kg/m2
Hypertension	
– Systolic blood pressure	<140 mmHg
– Diastolic blood pressure	<80 mmHg

Copied from Kenya national clinical guidelines for management of diabetes mellitus 2018.

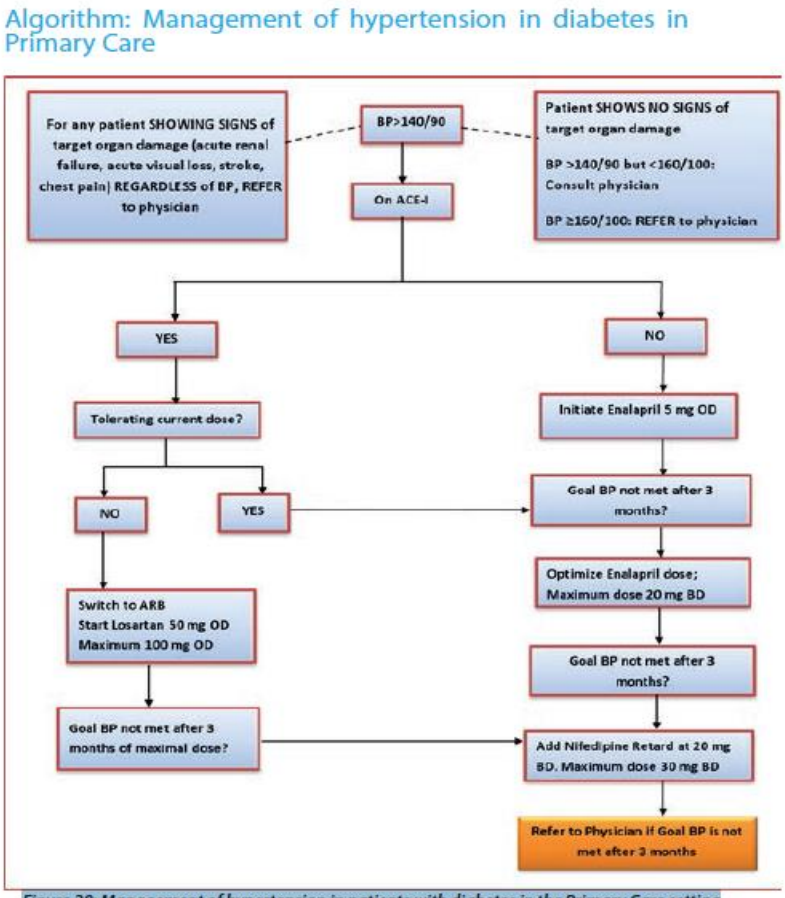

Figure 28: Management of hypertension in patients with diabetes in the Primary Care setting
Source: AMPATH

Figure 5: Management of hypertension in diabetes

Copied from Kenya national clinical guidelines for management of diabetes mellitus 2018.

Table 19: Desired level of lipids in patients with diabetes mellitus(LDL targets in the absence of CKD and CVD, DM in patients < 40 years, duration of <10 years)

Lipids	Target(mmol/L)	Target (Mg/dl
Total cholesterol	<4.8	<93.6
LDL cholesterol	<2.6	<-46.8
HDL cholesterol	>1.2 (Female) >1.0 (Male)	>19.8
Triglycerides	<1.7	<30.6

CKD-Chronic kidney disease, CVD- Cardiovascular disease

Table 20: Lipid targets for secondary prevention.

Lipids	Target (mmol/L)	Target (Mg/dL)
Total cholesterol	<4.8	<93.6
LDL cholesterol	<1.8	<32.4
HDL cholesterol	>1.2	>19.8
Triglycerides	<1.7	<30.6

Copied from Kenya national clinical guidelines for management of diabetes mellitus 2018.

Table 21: Targets for HbA1c, fasting plasma glucose and postprandial glucose in different patient types

Patient type	Target HbA1c	Target FPG	Target PPG
Young Low risk Newly diagnosed No cardiovascular disease	< 6.5%	4.0-7.0 mmol/l	4.4-7.8 mmol/l
Majority of patients	< 7%	4.0-7.0 mmol/l	5.0 -10.0 mmol/l
Elderly High risk (high cardio-vascular risk) Hypoglycaemic unaware Poor short-term prognosis	< 8%	4.0-9.8 mmol/l	< 11.0 mmol/l
Targets for other measurement			
Weight and height		BMI of 18.5 – 24.9 kg/m2	A 10% weight loss from the current weight if obese is recommend-ed
Waist circumference		**Male**	**Female**
		<90 cm	<84 cm
Blood pressure (mmHg)		**systolic**	**diastolic**
		<140 mmHg	< 90 mmHg
If persistent, microalbuminuria / proteinuria		<125 mmHg	<75 mmHg
Lipids **(fasting)**		**Male**	**Female**
Total cholesterol		<4.8 mmol/l	<4.8 mmol/l
LDL cholesterol		<2.6 mmol/l	<2.6 mmol/l
HDL cholesterol		>1.0 mmol/l	>1.3 mmol/l
Triglycerides		<1.7 mmol/l	<1.7 mmol/l

Copied from Kenya national clinical guidelines for management of diabetes mellitus 2018.

Table 22: Aerobic exercise recommended in T2DM

Definition	Intensity	Frequency	Examples
Activities that consist of rhythmic, repetitive and continuous movement of the same large muscle groups for at least 10 minutes at a time	Moderate:	Minimum 150 minutes per week (30 minutes per day for 5 days)	Cycling, brisk walking, continuous swimming, dancing, water aerobics, raking leaves, shamba work, house hold chores
	Or		
	Vigorous:	Minimum 75 minutes per week (30 minutes 3 times a week)	Brisk walking up an incline, jogging, aerobics, hockey, basketball, fast swimming, fast dancing
	Or		
	Equivalent combination of moderate and vigorous aerobic exercise		

Table 23: Anaerobic exercise recommended in T2DM

Definition	Frequency	Examples
Activities that require muscular strength to move a weight or work against a resistance load[a]	Two to three times per week: Start with one set of 10-15 repetitions at moderate weight Progress to two sets of 10-15 repetitions Progress to three sets at heavier weights	Exercise with weight machines, free weight lifting, Resistance band (e.g. Thera-Band®) exercises

**Resistance exercise should only be attempted if there are no contraindications to this kind of activity*

Copied from Kenya national clinical guidelines for management of diabetes mellitus 2018.

Table 24: Clinical Assessment for initial and follow-up visits for Type 2 Diabetes

	Initial visit	Three- to six-monthly visits	Annual visit
History			
Symptoms of hyperglycaemia* and duration of symptoms	X	X	X
Hypoglycaemic** symptoms	X	X	X
Relevant family history	X		
Other risk factors (e.g. gestational diabetes, PCOS, hypertension)	X	X	X
Relevant medical history (including TB infection and exposure)			
- Co-morbid conditions	X		X
- Symptoms of complications: Cardiovascular, neurological, bladder function, sexual function (i.e. erectile dysfunction or low libido), feet, visual, infection	X	X	X
Drugs			
- Side effects		X	X
- Adherence		X	X
- Allergies	X	X	X
Vaccinations			
- Pneumococcal (date)	X		X
- Influenza (date)	X		X
Lifestyle			
- Weight	X	X	X
- Physical activity/sedentary lifestyle	X	X	X
- Eating pattern	X	X	X
- Smoking	X	X	X
- Drug abuse	X	X	X
- Alcohol	X	X	X
Psychosocial support			
- Occupation	X		X
- Family and community support (support groups)	X		X
- Depression, anxiety and other mental disorders	X	X	X
Home monitoring of blood glucose (glucometer and strips; chart)	X	X	X
Physical examination			
Weight	X	X	X
Height	X	X	X
Body mass index (BMI) (kg/m^2)	X	X	X
Waist circumference (cm)	X	X	X
Heart rate and rhythm	X	X	X
Blood pressure in mmHg (both systolic and diastolic BP)	X	X	X
Injection sites, if appropriate	X	X	X
Feet			
- Inspection: Ulcers, soft tissue, deformities, Footwear	X	X	X
- Monofilament assessment	X		X
- Vibration sense using tuning fork, or pinprick sensation	X		X
- Ankle jerk	X		X
- Foot pulses	X		X
Oral cavity			
- Dental caries	X		X
- Gum disease	X		X
Eyes			
- Visual acuity	X		X
- Direct fundoscopy (dilated pupils), indirect fundoscopy, or fundus photographs	X		X[a]
Systemic examination			
Cardiovascular system examination	X		X

Special investigations			
Blood tests			
- Glucose	X	X	X
- HbA1c (Six-monthly if at target, otherwise three- monthly. Also, whenever treatment is adjusted)	X	X	X
- Lipids: Total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides	X		X
- Creatinine, and calculate estimated GFR	X		X
- Potassium	X		X
- TSH	X		X
- HIV	X		X
Urine			
- Glucose	X		X
- Protein			
- Ketones	X		X
- Leucocytes	X		X
Urine microalbuminuria	X		X
Uric acid	X		X
Full Hemogram	X		X
Liver Function Tests (ALT, AST, ALP)	X		X
Urine microalbuminuria	X		X
Uric acid	X		X
Full Hemogram	X		X
Liver Function Tests (ALT, AST, ALP)	X		X
ECG	X		X
Cancer screening (Pap smear, breast, PSA)	X		X
Cancer screening (Pap smear, breast, PSA)	X		X
Other important tasks			
Education: Self-management and lifestyle adjustment, including tobacco cessation, alcohol cessation, Hypoglycemia avoidance and treatment, nutrition and physical activity	X	X	X
Setting goals	X	X	X
Preconception counselling and family planning		X	X
Medication revision/adjustment	X	X	X
Immunizations	X		X

**Interval for retinopathy screening can be increased to once every 2 years if the last 2 examinations were normal; more frequent examinations are required in the presence of abnormalities.*

**Symptom of hyperglycaemia include polydipsia, headaches, blurred vision, polyuria, fatigue/body malaise, weight loss*

*** Symptoms/signs of Hypoglycemia- Nervousness or anxiety, sweating, chills and clammy extremities, irritability, confusion, including delirium, tachycardia, lightheadedness or dizziness, hunger and nausea, blurred/impaired vision, tingling or numbness in the lips or tongue, headaches, weakness or fatigue, mood changes, lack of coordination, nightmares or crying out during sleep, seizures, loss of consciousness.*

PCOS - polycystic ovarian syndrome

Copied from Kenya national clinical guidelines for management of diabetes mellitus 2018.

5.4.2 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD

Table 25: Summary of treatment targets for patients with diabetes

Risk factor	Target
BP	• Target SBP 130 mmHg for most adults, <130 mmHg if tolerated, but not <120 mmHg • Less-stringent targets, SBP 130 - 139 in older patients (aged >65 years)
Glycaemic control: HbA1c	• HbA1c target for most adults is <7.0% (<53 mmol/mol) • More-stringent HbA1c goals of <6.5% (48 mmol/mol) may be suggested on a personalized basis if this can be achieved without significant hypoglycaemia or other adverse effects of treatment • Less-stringent HbA1c goals of <8% (64 mmol/mol) or ≤9% (75 mmol/mol) may be adequate for elderly patients (see *section 6.2.1*)
Lipid profile: LDL-C	• In patients with DM at very high CV risk,[a] target LDL-C to <1.4 mmol/L (<55 mg/dL) and LDL-C reduction of at least 50%. • In patients with DM at high risk,[a] target LDL-C to <1.8 mmol/L (<70 mg/dL) and LDL-C reduction of at least 50%. • In patients with DM at moderate CV risk,[a] aim for an LDL-C target of <2.6 mmol/L (<100 mg/dL)
Platelet inhibition	In DM patients at high/very high CV risk
Smoking	Cessation obligatory
Physical activity	Moderate-to-vigorous, ≥150 min/week, combined aerobic and resistance training
Weight	Aim for weight stabilization in overweight or obese patients with DM, based on calorie balance, and weight reduction in subjects with IGT, to prevent the development of DM.
Dietary habits	Reduction of caloric intake is recommended in obese patients with T2DM to lower body weight; there is no ideal percentage of calories from carbohydrate, protein, and fat for all people with DM.

BP = blood pressure; CV = cardiovascular; DM = diabetes mellitus; HbA1c = haemoglobin A1c; IGT = impaired glucose tolerance; LDL-C = low-density lipoprotein cholesterol; SBP = systolic blood pressure; T2DM = type 2 diabetes mellitus.

[a]See *Table 7*.

Copied from the 2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD

5.4.3 ADA Guidelines

2018 ADA Clinical Guideline Update for Standards of Medical Care in Diabetes

1. Diabetes patients should have blood pressure measured at each routine visit as well as at home and multiple readings on separate days should be used to identify hypertension (≥140/90 mm Hg; Grade B recommendation).
2. Hypertensive patients with diabetes should be treated to achieve a systolic blood pressure of <140 mm Hg and a diastolic blood pressure of <90 mm Hg (Grade A recommendation), whereas lower pressure ratios (eg, 130/80 mm Hg) should be the goal for patients with diabetes deemed at high risk for cardiovascular disease (CVD; Grade C recommendation).
3. Lifestyle interventions, including exercise, weight loss, smoking cessation, and reducing trans fat and cholesterol intake, are recommended for lowering blood pressure (Grade B recommendation) and lipids (Grade A recommendation).
4. At diabetes diagnosis and/or initiation of statins or other lipid-lowering treatment, a lipid profile should be obtained at initial medical evaluation as well as every 5 years following evaluation if the patient is age <40 (Grade E recommendation).
5. Lifestyle therapy should be an adjunct to high-intensity statin therapy in patients with diabetes and atherosclerotic CVD (ASCVD; Grade A recommendation).
6. Patients with diabetes age <40 with other ASCVD risk factors (Grade C recommendation) as well as patients between 40 and 75 (Grade A recommendation) and >75 (Grade B recommendation) without ASCVD are recommended to undergo moderate-intensity statin therapy in addition to lifestyle intervention.
7. In patients with diabetes and ASCVD who have low-density lipoprotein cholesterol ≥70 mg/dL and who are taking a maximally tolerated statin dose, additional low-density lipoprotein cholesterol-lowering treatments are recommended, including ezetimibe or a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor (Grade A recommendation).
8. Patients with diabetes who have a history of ASCVD should use 75 to162 mg/d of aspirin for secondary prevention (Grade A recommendation), whereas patients with an aspirin allergy are recommended to take 75 mg/d of clopidogrel (Grade B recommendation).
9. Patients with either type 1 or 2 diabetes at an increased risk for CVD (eg, family history of ASCVD, dyslipidemia, smoking, hypertension, or albuminuria) but no risk for bleeding may use 75 to162 mg/d of aspirin as their primary prevention strategy (Grade C recommendation).
10. As long as ASCVD risk factors are effectively treated, asymptomatic patients are not recommended to undergo routine screening for coronary artery disease (Grade A recommendation).

Figure 6: 2018 ADA Clinical Guideline Updates for Standards of medical care in diabetes.

Copied from 2018 ADA Clinical Guideline Updates for Standards of medical care in diabetes

5.4.4 ACC/AHA ASCVD Risk Calculator

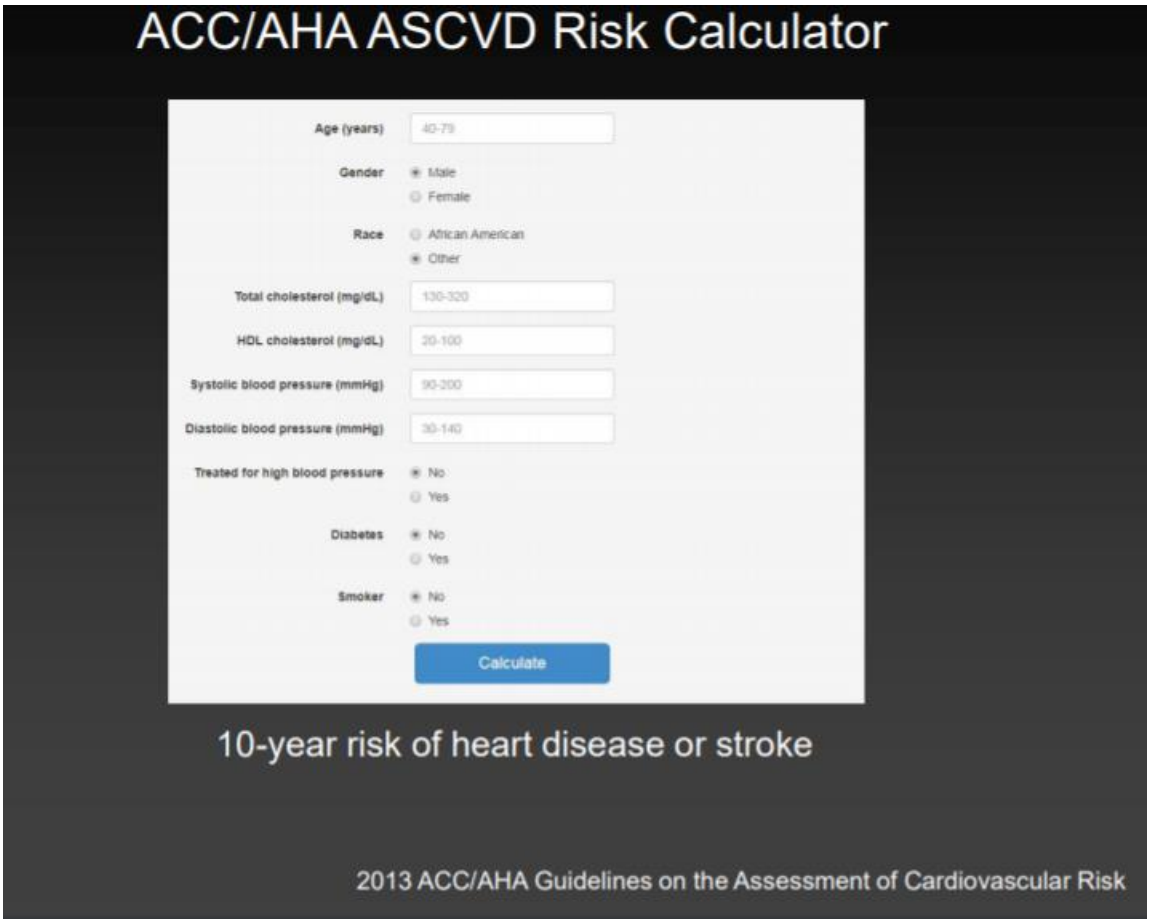

Figure 7: ACC/AHA ASCVD RISK CALCULATOR

Downloaded from acponline.org/system/files/documents/about_acp/chapters/oh/hypertension_guidelines.ppt.pdf accessed on 16/03/2020.

5.4.5 ESC/EASD risk stratification

Very high risk	Patients with DM **and** established CVD **or** other target organ damage* **or** three or more risk factors§ **or** early onset of T1DM of long duration (>20 years)
High risk	Patients with DM duration ≥10 years without target organ damage plus any other additional risk factor
Moderate risk	Young patients (T1DM aged <35 years or T2DM aged <50 years) with DM duration <10 years, without other risk factor

DM, diabetes mellitus; CVD, cardiovascular disease; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus* Proteinuria, renal impairment defined as eGFR <30mL/min/1.73m^2, left ventricular hypertrophy, or retinopathy § Age, hypertension, dyslipidemia, smoking, obesity

Figure 8. ESC/EASD risk stratification in patients with diabetes.

5.5 Consent forms

5.5.1 Participant information and consent form explanation for healthcare practitioners for enrollment in the study. (To be administered in English).

- Title of Study:

AN AUDIT OF CARDIOVASCULAR RISK MANAGEMENT IN TYPE 2 DIABETES MELLITUS AT KENYATTA NATIONAL HOSPITAL

- Principal Investigator\and institutional affiliation:
    i. Dr. Simeon Ogwang' Jowi\ Registrar at the Department of Clinical Medicine and Therapeutics, University of Nairobi.
- Co-Investigators and institutional affiliation:

i. Professor E.N Ogola, Consultant cardiologist, Professor of Medicine, Department of Clinical Medicine and Therapeutics, University of Nairobi
ii. Professor C.F Otieno, Consultant endocrinologist, Professor of Medicine, Department of Clinical Medicine and Therapeutics, University of Nairobi
iii. Professor T.M Munyao, Consultant dermatologist, Professor of Medicine, Department of Clinical Medicine and Therapeutics, University of Nairobi
iv. Dr. Judith Kwasa, Consultant Neurologist, Lecturer Department of Clinical Medicine and Therapeutics. University of Nairobi.

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No.P434RR

WHAT IS THIS STUDY ABOUT?

The researchers listed above are recruiting healthcare practitioners primarily involved in management of type 2 Diabetes Mellitus patients. The purpose of the interview is to assess healthcare practitioners' knowledge on cardiovascular risk factor control among type 2 DM patients. In this research study, the participants' knowledge will be assessed using best response multiple choice questionnaires on management of cardiovascular risk factor control in type 2 diabetes mellitus with respect to current guidelines.

There will be approximately seventy four participants in this study chosen via non-probability purposive sampling. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen: You will be given a questionnaire containing twenty three questions. Completion of the questionnaire will take approximately thirty minutes. The questionnaire will cover five sections that are integral to management of cardiovascular risk in type 2 DM namely: risk stratification, management of blood pressure, management of glycaemia, management of dyslipidaemia, lifestyle modification and use of anti-platelets. After completion of the questionnaire your form will be taken by either the PI or research assistants, and that will conclude your participation in the study. All the information provided will be held absolutely confidential and cannot be used against you.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. To that effect, we will keep everything you answer as confidential as possible. We will use a coded study number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you. For the sake of the completeness of the study we would require that you answer all the questions. A blank response will be considered as wrong. Other than that, this study poses no other risks.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

The information you provide will help us improve on knowledge and practice in management of cardiovascular risk in type 2 diabetics at Kenyatta National Hospital and is thus a valuable contribution not only to science but also to the population of the country.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Participating in this study will not cost you anything

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement:

I have read this consent form or had the information read to me. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study (tick appropriately): Yes ☐ No ☐

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ Date: _____

Signature: _____

Role in the study: _____

For more information contact Dr. Simeon Ogwang' Jowi at either:

P.O.BOX 19624-00202

Nairobi.

simjowi@gmail.com

0788675803

5.6 Budget

The costs were borne by the principal investigator.

Table 26*: *Study budget

ITEM	COST
Stationery	**Ksh 18250**(cost of printing the necessary study tools: audit tool and questionnaires plus the required stationery required for the data entry)
Statistician	**Ksh 40,000**
Research Assistants	**Ksh 40,000**(cost of hiring 2 research assistants at ksh10,000 a month over the 2 months of data collection and entry)
Ethics submission fees	**Ksh 2,000**
Total	**Ksh 100,250**