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STATIN THERAPY AMONG DIABETIC PATIENTS IN RWANDA

A dissertation submitted to College of Medicine and Health Sciences, School of Medicine and Pharmacy in partial fulfillment for the requirement of award of a Master of medicine in Internal Medicine, University of Rwanda.

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SEPTEMBER 5, 2022

DECLARATION

DECLARATION

I, Cedric KWITONDA, hereby declare to the best of my knowledge and certify that the work presented in this dissertation entitled'' **Statin therapy among diabetic patients in Rwanda**" is entirely my original work. This has never been submitted or presented in whole or in part to any other university for the award of a degree.

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DEDICATE

To God almighty

To my late parents

To my wife and daughter

To my brothers

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This dissertation was possible owing to the continuous guidance and support from various persons to whom I thank.
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“May our Almighty God bless you all ”.

Dr. Cedric KWITONDA

LIST OF ABBREVIATIONS

LDL-C: Low Density Lipoprotein Cholesterol

HDL: High Density Lipoprotein

ASCVD: Atherosclerotic Vascular Disease

HPS: Heart Protection Study

AHA/ACC: American Heart Association/American College of Cardiology

CHD: Coronary Heart Disease

4 S: Scandinavian Simvastatin Survival Study

CAD: Coronary Artery Diseases

CV: Cardiovascular

NNT: Number Needed to Treat

HMG-CoA: 3-Hydroxy-3-Methyl-Glutaryl-Coenzyme A

CHUB: Centre Hospitarier Universitaire de Butare

CHUK: Centre Hospitarier Universitaire de Kigali

RDA: Rwanda Diabetic Association

BMI: Body Mass Index

IRB: Institutional Review Board

PAD: Peripheral Arterial Disease

CBHI: Community Based Health Insurance

FARG: Fonds d` Assistance aux Rescapés du Génocide

T2DM: Type 2 Diabetes Mellitus

ABSTRACT

Background: We conducted a cross-sectional study of 384 outpatients diabetics aged between 40-75 years attending 2 teachings hospitals (CHUK and CHUB), and one private Rwanda diabetic association clinic were included in the study for a period of 3 months, since April until June 2022. We assessed the percentage of eligible diabetic patients taking statins, and patients were divided into groups for primary or secondary prevention based on their prior history of ASCVD. Logistic regression was used to determine the association between primary or secondary statin prescription.

Purpose: the study purpose is to assess the extent of statin therapy among study participants for primary and secondary cardiovascular diseases prevention.

Results: 384 patients were enrolled in the study; their average age was 58 (+/- 9.8), and 37.2% of them were between 50-60 years. Among the participants, 284 (74%) were females, 378 (98.4%) had insurance, and 253 (65.9%) of the diabetes were hypertensive.

The mean (± SD) of ACC/AHA 10 years ASCVD risk scores was found to be 17.06 (±15.51),204 of participants (66.4%) had a high risk level of 10 years cardiovascular risk and 103(33.6%) had a moderate risk level. Among 384 patients, only 7(1.7 %) were on statins,3 of 7 (42.8%) as primary prevention and 4 among 7(57.2%) as secondary prevention of atherosclerotic cardiovascular diseases. A binary logistic regression was conducted on variables which were significantly associated from bivariate analysis that include gender, health insurance, atherosclerotic cardiovascular disease and hypertension for controlling for confounding and effect modification. The results revealed that female patients are 10.3 times less likely to receive statin than male patients (AOR=10.35, 95% CI: 1.003-46.865, P=0.042). Non-insured diabetic patients in this study were 2.15 times less likely to receive statin (AOR=2.15, 95% CI: 1.001-7.027, P=0.006) than those with insurance scheme. Patients without atherosclerotic cardiovascular disease were 1.602 times less likely to be on statin than those with established ASCVD (AOR=1.602, 95% CI: 1.102 - 4.219, P=0.008). Patients without hypertension were 2.41times less likely to use statin than hypertensive (AOR=2.41, 95% CI: 1.023-8.206, P=0.031).

Conclusion: According to the findings of this study, the majority of diabetic patients in Rwanda are not on statin therapy and physicians do not adhere to the international guidelines recommendations on statins therapy among diabetics. These findings call for an improvement in diabetic standard of care by complying to the evidence based guidelines recommendations.

Keywords: statins, therapy, atherosclerotic vascular diseases.

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Chapter I: Introduction

I.1.Background

Diabetes mellitus has about a twofold excess risk for a wide spectrum of vascular diseases, independent of other traditional risk factors. Cardiovascular disease, including peripheral artery disease, cerebrovascular disease, and coronary artery disease, is common and accounts for more than two-thirds of deaths in people with type 2 diabetes(1) (2). The global prevalence of diabetes in 2021 was estimated at 537 million people between the ages of 20 and 79. This age group accounts for 10.5% of the world population. The total diabetic population is projected to increase to 643 million (11.3%) by 2030 and 783 million (12.2%) by 2045. An estimated 240 million people worldwide have undiagnosed diabetes. Meaning almost one in two adults are unaware they have diabetes. Nearly 90% of undiagnosed diabetics live in low and middle-income countries. More than half of people with diabetes remain undiagnosed in Africa, Southeast Asia and the Western Pacific (3).

In Rwanda diabetes is estimated to have an prevalence of 3 %,and 1 in 38 adults has diabetes with a prevalence of 2,7 % in adults population of 20-79 years (3).

The 2020 year book report, death related to cardiovascular diseases were ranked as the third leading cause of death in Rwanda, representing 7,1 % of all causes of death(4). and this should bring attention on possible preventive measures.

Statins have proven to be beneficial in reducing a first cardiovascular event in type 2 diabetic patients regardless of their level of LDL-cholesterol(5).

I.2.Rationale

Given the rising burden of cardiovascular related morbidity and mortality in Rwanda, preventive measures on modifiable cardiovascular risk should be a priority. One of these measures for diabetic patients in addition to changing one's lifestyle, is lipid-lowering treatment.

While in developed countries there is documented high use statin among diabetic patients for prevention of ASCVD(6) ,studies showed underuse of lipid lowering therapy in sub-Saharan Africa (7)(8).

In a study done in Tanzania by T.Bideberi et al. on statin prescription patterns and associated factors among patients with type 2 diabetes mellitus attending a diabetic clinic at Muhimbili National Hospital find under prescription of statin among eligible diabetic patients, only 47.3% were on statins (7).

The aim of this study is to assess the extent of statin therapy among diabetic patients as primary or secondary prevention of cardiovascular diseases in Rwanda and to enhance awareness of physicians to comply to the international guidelines.

No baseline investigation evaluating statin medication use among diabetics has been carried out in Rwanda, as far as we are aware. We hope this study will help to improve diabetes care in terms of ASCVD prevention.

I.3. Literature review

Diabetes is a chronic, metabolic disease characterized by increased levels of blood sugar, which leads overtime to complications on the heart, blood vessels, eyes, kidneys and nerves. These complications are typically clinically silent until a advanced stage(9).

The majority of people with diabetes live in low and middle-income countries, and the number of people with diabetes is projected to rise to 578 million by 2030 and 700 million by 2045. Diabetes was responsible for an estimated 1.5 million deaths in people under the age of 70 in 2019(3).

Macro vascular complications including ischemic heart diseases, stroke and peripheral arterial diseases are a major cause of morbidity and mortality in diabetics patients(10).

This should bring attention on preventive measures of ASCVD in diabetic patients. In addition to life style modification and exercise, statins have shown to be beneficial in preventing first cardiovascular event(5)(11)(12)(13)(14) .the collaborative atorvastatin diabetes study, reported a significant reduction in coronary event by 36% and stroke by 48% in a diabetic population ,the beneficial effect of statin was evident in this study and resulted in an early termination (2 years in advance)(5).

A meta-analysis of 14 randomized trials of statin therapy, including data from 18000 diabetic patients has shown a 9% proportional reduction in all causes mortality and for every mmol/l decrease in LDL cholesterol, vascular mortality is reduced by 13%. (15).

In heart protection study, 20 536 patients were randomized in 69 sites with a 5 years follow up, intervention was simvastatin 40 mg vs placebo, HPS showed a reduction of cardiovascular death by 13% and major vascular event by about one quarter in simvastatin group (16).

Given the positive effect of statins in primary prevention of cardiovascular diseases numerous guidelines recommend use of statin as primary prevention among diabetic patients of 40 to 75 years(17)(18)(19).

The 2013 AHA/ACC guidelines advocate an approach based on the global risk estimate. Individuals with type 1 or type 2 diabetes between the ages of 40 and 75 who have baseline untreated LDL-c values between 70 and 189 mg/dl should be separated into high and low risk groups and treated with either high or moderate intensity statins, according to the panel.

This classification is based on the results of atherosclerotic cardiovascular diseases (ASCVD) outcomes calculations.

By entering specific risk variables, the ACC/AHA Calculator can predict the 10-year risk of the first ASCVD event (non-fatal myocardial infarction or CHD mortality, or fatal/non-fatal stroke). It uses risk equations generated from samples of four cohorts of the American population. The 10-year risk is based on her first ASCVD incident in a patient who has never had ASCVD. This calculator is for non-Hispanic African Americans and non-Hispanic whites ages 40-75. The

guidelines advocate aggressive statin treatment for diabetic patients whose 10-year ASCVD risk exceeds 7.5%. Moderate-strength statins are recommended if the risk is below this level.

The panel defines high-intensity therapy as statin therapy that lowers LDL-c by 50% or more from baseline. LDL-c levels are reduced by 30-50% with moderately intensive treatment. The evidence of benefit is less evident in people under the age of 40 or older than 75.

When choosing whether to begin or escalate statin medication in these circumstances, the AHA/ACC panel deems it fair to assess the potential for ASCVD benefits while taking into accounts the patient's preferences and any potential side effects.(20)

Statins are effective in prevention of atherosclerotic vascular diseases recurrence. The secondary prevention benefit of statin has been shown by multiple studies(21)(22)(23) including, in 4 S study where they randomized 4444 patients with prior CAD and dyslipidemia to simvastatin vs placebo with a mean follow up of 5.4 years and the study was halted early because of absolute risk reduction of 3.3% in all causes mortality within the simvastatin group, The trial also demonstrated reductions in multiple other endpoints including major coronary event (NNT 15), CV mortality (NNT 31), and coronary interventions (NNT 17)(22).

Statins mechanism of action

Statins function by competitively inhibiting the HMG-COA reductase active site in the mevalonate pathway. By preventing access to the substrate, inhibition of this site prevents HMG-COA from being converted to mevalonic acid.

This lowers hepatic cholesterol synthesis, leading to increased HMG-COA reductase production and increased cell surface LDL receptor expression. As a result, there is an increased blood stream clearance of circulating LDL-c with reduction of LDL level by 20 to 50 % (24).

Statins may have additional effects which include improvement in endothelial function, stabilization of atherosclerotic plaque, anti-inflammatory, immunomodulatory antithrombotic effect, effects on bone metabolism. These additional benefits are thought to arise due to inhibition of the synthesis of isoprenoid intermediates of the mevalonate pathway(24).

Study question

What is the extent of statin therapy among eligible diabetic patients of 40-75 years in Rwanda?

What proportion on statin therapy is for primary or secondary prevention of ASCVD?

What are the 10 year ASCVD risk classification of our study participants?

Research hypothesis

There is under prescription of statins among diabetic patients in Rwanda.

General objective

To assess the extent of statin therapy among diabetic patients between 40-75 age.

Specific objectives

1.to assess use of statin as primary prevention of cardiovascular diseases among diabetic patients in the study group

2.to evaluate the use of statin as secondary prevention of cardiovascular diseases in the study group

3.Evaluate 10 years cardiovascular risk by using ACC/AHA 10 years ASCVD score

4.to assess the association between the level of cardiovascular risk and prescribed statin intensity.

Chapter II. Methodology

II.1. Study design

This was a multicenter cross sectional study assessing the extent of statin therapy in

diabetic population of 40-75 years.

II.2. Study populations

Diabetics patients between 40-75 of age attending outpatient IM clinics at 2 teaching

hospitals (CHUB, CHUK) and RWANDA diabetic association clinic.

II.3. Study settings and period

Study was conducted at 3 outpatient diabetic clinics:

Including 2 publics teaching hospitals: BUTARE teaching hospital(CHUB)

KIGALI teaching hospital(CHUK)

And 1 private clinic which is RWANDA diabetic association clinic located in Kigali.

Study was conducted in a period of 3 months from April till June 2022

II.4. Inclusion criteria

Diabetic patients between 40-75 age attending outpatient clinics (type 1 or type 2) with or

without established cardiovascular diseases(without known history of stroke,ischemic heart diseases,peripheral arterial diseases and abdominal aorta aneurysm).

Patients accepting to participate in the study

II.5. Exclusion criteria

Were excluded: - diabetics patients under 40 and above 75 years.

-patients who will not accept to participate in study.

II.6. Sample size

For sample size determination we used Yamane formula

$$n = \frac{N}{1 + Ne^2}$$

N: population size, n: corrected sample size, e: margin of error = 0.05

Our sample size was 384 diabetics patients.

II.7. Data collection

Data were collected by using pre-established questionnaires.

Demographic data were collected including: age, sex, occupation, educational attainment, and marital status. Other information like smoking history, hypertension, ischemic heart diseases, stroke or peripheral vascular disease were recorded.

We also recorded data on the use of statins based on their dose intensity(lower intensity, moderate intensity and high intensity),lower intensity: atorvastatin< 10 mg/day, rosuvastatin <5 mg /day, simvastatin <20mg/day and lovastatin <40mg/day, moderate intensity: atorvastatin 10-40 mg/day, rosuvastatin 5-20 mg/day, simvastatin 20-80mg/day and lovastatin > 40mg/day, high intensity: atorvastatin >40 mg/day, rosuvastatin > 20 mg/day, and simvastatin > 80 mg/day and anthropometric measurements (weight, height and BMI).

We measured and recorded blood pressures, and collect from the electronic record the lipid profile done within 1 year.

For this study, we evaluated the extent of statin therapy among the participants.

The primary outcome measure was statin coverage as primary or secondary prevention of cardiovascular diseases among participants.

The 10 year cardiovascular risk was calculated by ACC/AHA 10 years ASCVD risk calculator.

Questionnaire was translated in Kinyarwanda by the study team for helping those not fluent in English. The survey was administered in accordance with the guidelines.

II.8. Data entry and analysis

Clean data were imported from MS Excel and analyzed using IBM SPSS version 26. Demographic, clinical data and statin utilization were analyzed and present categorical variables as frequencies(percentile) and continuous variables as means (standard deviation) or their 95% confidence interval as appropriate. Logistic regression was used for establishing the relationship between variables.

II.9. Study justification

To our knowledge, there is no study done in Rwanda assessing the prevalence and pattern of statin therapy among diabetic patients and we hope this study will help to improve on the standardized diabetic health care on primary and secondary prevention of cardiovascular diseases.

This study will help also to get data on statin therapy in Rwanda and in sub-Saharan Africa as there is few datas on statin therapy in diabetics patients in sub-Saharan Africa.

II.10. Data security

Locked cabinets were used to store all paper based study data and were only accessible to the study team, the principal investigator was in charge of the data security.

The electronically generated data were identified and files were password protected. Access to data were restricted to the study team.

II.11. Ethical Consideration

Ethical clearance was obtained from the Institutional Review Board (IRB) as well as the hospitals study sites ethical committees. Study participants provided written informed consent prior to study enrollment.

II.12. Conflict of interest

The study collaborators declare no conflicts of interest in this study.

CHAPTER III: RESULTS

III.0. Introduction

This chapter presents the findings from this study on the prevalence of statin prescription among diabetic patients (Type 1 and Type 2) aged between 40-75 in University Teaching Hospital of Kigali (CHUK), The University Teaching Hospital of Butare (CHUB) and 1 private clinic which is RWANDA diabetic association clinic located in Kigali. All 384 randomly sampled diabetic patients participated in the study. Descriptive analysis was used to understand the characteristics of respondents, bivariate analysis using chi-square test was used to test for relationship between each independent variable and statin use among diabetic patients. Independent variables with a significant association with statin use were included in logistic regression for adjusting multivariable correction and control of confounding variables. Both graphs and tables were used to present the findings in line with the specific objectives.

III.1. SOCIO DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF STUDY PARTICIPANTS

The socio demographics of diabetic patients included in this study were age, gender, type of diabetes, marital status, economic class (UBUDEHE Category), employment status, Body mass Index(BMI), Health Facility, education level and availability of health insurance.

The mean (± SD) age of diabetic patients participated in the study was 58 (±9.8) years with 92(24%)between 40-50 years, 143(37.2%) between 50-60 years, 95(24.7%) were aged between 60-70 while only 54(14.1%) were aged above 70 years. Three-fourths of all participants 284 (74%) were females. 365(95.6%) of our participants had diabetes of type 2. The mean (± SD) BMI of our diabetic patients was 26.7(±4.8) kg/m^2. According to socio-economic class (UBUDEHE Category), most of diabetic patients participated in the study 267(69.5%) were in third category, 91(23.7%) were in second category, 23(6.0%) were in first category and only 3(0.8%) were in the Fourth Category. Participants had different employment status, however 243(63.3%) were farmers, 47(12.2%) were unemployed, 64(16.7%) were self-employed, 9(2.3%) had formal employment and 4(1%) while 17(4.4%) were students and retired respectively.

The study was conducted in three health facilities, half 193(50.3%) of participants were from CHUB, 177(46.1%) were from CHUK and only 14(3.6%) were from clinic of Rwanda Diabetic association (RDA). More than a half 214 (55.7%) of participants attained primary education, 92(24%) had no formal education and only 78(20.3%) had chance to continue to higher education. Regarding the insurance, 378(98.4%) of study participants were insured.

The research findings revealed that 253(65.9%) had hypertension while 131(34.1%) were not hypertensive. Only 40(10.4%) were smokers while 344(89.6%) were not smokers.

Total cholesterol was classified in three categories according to the results obtained, when it was lower than 200 mg/dl was considered normal, between 200 and 239 mg/dl as intermediate and above 240mg/dl was considered high, Total cholesterol level was measured from 334 (87%) diabetic patients, the results showed that 228(59.4%) of them had normal level of total

cholesterol, 80(20.8%) had intermediate level whereas 26(6.8%) had a high level of total cholesterol.

LDL cholesterol was measured from 320 (83.3%) diabetic patients and as shown in the table below (Table 3.1), 87(22.7%) had a normal level of LDLC, 100(26%) had a LDLC level above borderline, 94(24.5%) had a borderline high level whereas 26(6.8%) had a high level of LDLC but only 13(3.4%) had a very high level of LDLC.

HDL Cholesterol is considered low when is below 40mg/dl and below 50mg/dl for men and women respectively, above these levels is said to be normal. The research findings as displayed in table 1, revealed that from 227(59.1%) female diabetic patients, 148(65.2%) had low HDL cholesterol and 34(34.8%) had normal HDL cholesterol. Among 102(26.6%) male diabetic patients, 34(33.3%) had lower HDL cholesterol comparing to 68(66.7%) had normal level of HDL cholesterol.

Triglycerides are classified into different levels, below 150 mg/dl is considered normal, between 150-199mg/dl is considered borderline high, between 200-499 is at high level and classified as very high level of Triglycerides when is above 500mg/dl. The research findings from our study indicated that among 324(84.4%) diabetic patients who measured their triglycerides, 223(58.1%) had a normal triglyceride level, 43(11.2%) had a borderline high level, 57(14.8%) had a high level and only one (0.3%) had a very high triglyceride level. See the table 4.

Table 1:Socio demographic and clinical characteristics of study participants.

Variables	Description	Frequency (n=384)	Percent (%)
Age	**Mean ± SD =** (57.9 ± 9.8)		
	40-50	92	24.0
	50-60	143	37.2
	60-70	95	24.7
	Above 70	54	14.1
Gender			
	Male	116	30.2
	Female	284	74.0
Diabetes Type			
	Type 1	17	4.4
	Type 2	367	95.6
Marital Status			
	Single	20	5.2
	Married	233	60.7
	Divorced/Widowed	131	34.1
BMI			
	Underweight	19	4.9
	Normal weight	114	29.7
	Overweight	158	41.1
	Obese	93	24.2
UBUDEHE Category			

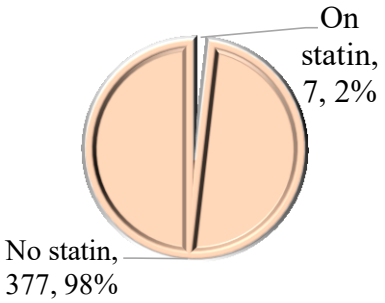
	Category 1	23	6.0
	Category 2	91	23.7
	Category 3	267	69.5
	Category 4	3	0.8
Employment Category			
	Unemployed	47	12.2
	Self-employed	64	16.7
	Farmer	243	63.3
	Formal employment	9	2.3
	Student	4	1.0
	Retired	17	4.4
Health Facility			
	CHUK	177	46.1
	CHUB	193	50.3
	RDA	14	3.6
Education Level			
	No education	92	24.0
	Primary	214	55.7
	Higher education	78	20.3
Health Insurance			
	Insured	378	98.4
	Non-insured	6	1.6
Hypertension			
	Yes	253	65.9
	No	131	34.1
Smoking			
	Yes	40	10.4
	No	344	89.6
Total Cholesterol Mean ± SD = (57.9 ± 9.8)			
	Normal	308	92.2
	High	26	7.8
LDL Cholesterol Mean ± SD = (57.9 ± 9.8)			
	Normal	277	86.6
	High	43	13.4
HDL Cholesterol-Male Mean ± SD = (57.9 ± 9.8)			
	Low	34	33.3
	Normal	68	66.7
HDL Cholesterol-Female Mean ± SD = (57.9 ± 9.8)			
	Low	148	65.2
	Normal	79	34.8
Triglycerides Mean ± SD = (57.9 ± 9.8)			
	Normal	266	82.1
	High	58	17.9

III.2. USE OF STATIN AS PRIMARY OR SECONDARY PREVENTION OF CARDIOVASCULAR DISEASES AMONG DIABETIC PATIENTS

III.2.1. Prevalence of statin use as a prevention for cardiovascular disease.

Statin is used as a primary prevention of cardiovascular disease (CVD) among diabetic patients who have never acquired any cardiovascular disease and as a secondary prevention for the diabetic patients who has established cardiovascular disease such as ischemic heart diseases, stroke, peripheral arterial disease (PAD) and abdominal aneurysm

Figure 3.1: Use of statin as prevention for cardiovascular disease.



The study findings showed that among 384 diabetic patients only 7 (2%) use statins as prevention of cardiovascular disease (4: Atorvastatin, 2: Rosuvastatin, 1: Simvastatin). Among these patients only 3(42.8%) use statin as primary prevention for cardiovascular disease and 4(57.2%) use statin as secondary prevention for cardiovascular disease. See the figure 3.1 above

III.2.2. 10 years cardiovascular risk by using ACC/AHA 10 years ASCVD score

The mean (± SD) of ASCVD scores taken was found to be 17.06 (±15.51), The ASCVD scores taken were classified into Low, intermediate, borderline and high levels. As shown in the table below (Table 2). From 384 diabetic patients participated in the study, ACC/AHA 10 years ASCVD score were calculated from 307(80%) patients, the findings showed that 75(19.5%) had a low level of ASCVD, 28(7.3%) had a borderline low level ,110(28.6%) had intermediate level while 94(24.5%) had high level.

Table 2:10 years cardiovascular disease Risk levels

10 Years CDV risk Levels	Frequency (N)	Percent (%)
Low	75	19.5
Intermediate	110	28.6

Borderline	28	7.3
High	94	24.5
Missing	77	20.1

According to American heart association (AHA), in diabetics patients two categories (moderate and high) should be formed, which generate the following results as shown on the table 3 below. Among 307(80%) diabetic patients to whom ACC/AHA 10 years ASCVD scores were calculated, 204(66.4%) had a high risk level of 10 years cardiovascular risk and 103(33.6%) had a moderate risk level.

Table 3: 10 years cardiovascular disease Risk levels according to AHA

AHA Classification of 10years CVD	Frequency (N)	Percent (%)
Intermediate	103	33.6
High	204	66.4

III.2.3. the prescription of statin medications according to lipid profile

The research findings as shown in the table 4 below revealed a worrisome gap in uptake of statin medications among diabetic patients, despite known beneficial effect of statin in preventing first or secondary cardiovascular event in diabetic patients. In our study only 6 (1.8%) diabetic patients with normal total cholesterol level are on statin.

Diabetic patients with very high LDL Cholesterol should be on statins, however from our research one is on statins and three who are on statins have normal level of LDL Cholesterol. 3(2.9%) males with normal HDL Cholesterol were on statins compared to 1(0.4%) woman who was on statin. One female as well as one male with low level of HDL cholesterol were on statin.

Three (2.9%) who are on statins have a normal level of triglycerides, 2(0.6%) had borderline high level and only 1 (0.3%) patient on statin had high level of triglycerides.

Table 4:prescription of statin according to Lipid profile.

Lipid Profile		On Statins			
		No		Yes	
		Freq (n)	Percent (%)	Freq (n)	Percent (%)
Total Cholesterol Levels					
	Normal	222	56.5	6.0	1.8
	Intermediate	80	24.0	0.0	0.0
	High	26	7.8	0.0	0.0
LDLC Level					
	Normal	84	26.3	3.0	0.9
	Above borderline	98	30.6	2.0	0.6
	Borderline high	93	29.1	1.0	0.3
	High	26	8.1	0.0	0.0
	Very High	13	4.1	0.0	0.0
HDLC Category-Male					
	Low	33	32.4	1.0	1.0
	Normal	65	63.7	3.0	2.9
HDLC Category-Female					
	Low	147	64.8	1.0	0.4
	Normal	78	34.4	1.0	0.4
Triglycerides Level					
	Normal	220	67.9	3.0	0.9
	Borderline High	41	12.7	2.0	0.6
	High	56	17.3	1.0	0.3
	Very High	1	0.3	0.0	0.0

III.3. The association between level of cardiovascular risk and prescribed statin intensity.

The study results as shown in the Table 5 revealed that only one (0.3%) among 137 (35.7%) diabetic patients with low risk level of cardiovascular disease was on moderate statin prescription, 2 (0.5%) among 113 (29.4%) patients with intermediate risk level of ASCVD were on moderate statin intensity, 4 (1.0%) among 106 (27.6%) diabetic patients with high ASCVD risk level were on High dose of statin intensity while none of the 28(7.3%) diabetic patients with borderline risk level of ASCVD was on statin intensity.

The chi-square test of independence for association, showed that there is a significant relationship (p=0.03, p<0.05) between ASCVD risk level and statin dose received by diabetic patient, the higher the ASCVD risk level, the high dose of statin dose received vice-versa.

Table 5:The association between level of cardiovascular risk and prescribed statin intensity.

ASCVD Risk Level	Statin Level		Not on Statin n(%)	P-Value
	Moderate n(%)	High n(%)		
Low	**1 (0.3%)**	0 (0.0%)	136 (35.4%)	0.03
Intermediate	**2 (0.5%)**	0 (0.0%)	111 (28.9%)	
Borderline	0 (0.0%)	0 (0.0%)	28 (7.3%)	
High	0 (0.0%)	**4 (1.0%)**	102 (26.6%)	
Total	3 (0.8%)	4 (1.0%)	377 (98.2%)	

III.4. THE FACTORS ASSOCIATED WITH NO USE OF STATINS AMONG DIABETIC PATIENTS

Bivariate analysis was conducted to study the association between independent variables that include socio-demographic characteristics of diabetic patients and dependent variable, which is statin use, P-Value (p<0.5) was considered significant on 95% confidence level.

As shown is Table 6, gender of diabetic patient was associated with statin use (p=0.028), more female patients tend not to receive statin 2(0.5%) than male patients 5(1.3%). The body mass index (BMI) of patient was not associated with use of statin as well as their type of diabetes, marital status, UBUDEHE category, employment status and their education level.

Non-insured patients are less likely to take statin (p<0.001) than insured patients, 7(1.8%) of patients who received statin are insured (CBHI=5, Radiant=1 and FARG=1). Tobacco smoking was not associated with use of statin but having atherosclerotic cardiovascular disease was associated with use of statin (p<0.001) with 4 (57.1%) of patients on statin have atherosclerotic cardiovascular disease. Hypertension was associated with statin use with 6(85.7%) of patients received statin have hypertension (p=0.042) whereas 373(97.1%) of patients without ASCVD did not use statins. Lipid profiles are not associated with no-statin use among diabetic patients (p>0.05).

Table 6:The factors associated with use of statin among diabetic patients

Variables	Description	Received Statin		P-Value
		Yes (%)	No n(%)	
Diabetes type				
	Type 1	0(0.0)	17(4.4)	0.726
	Type 2	7(1.8)	360(93.8)	
Gender				
	Male	5(1.3)	111(28.9)	**0.028**
	Female	2(0.5)	266(69.3)	
Age				
	Age	7(1.8)	377(98.2)	**0.000**
BMI				
	Underweight	0(0.0)	19(4.9)	
	Normal	1(0.3)	113(29.4)	
	Overweight	4(1.0)	154(40.1)	
	Obese	2(0.5)	91(23.7)	0.700
Marital status				
	Single	0(0.0)	20(5.2)	
	Married	4(1.0)	229(59.6)	
	Divorced	3(0.8)	128(33.3)	0.761
UBUDEHE				
	UBUDEHE 1	0(0.0)	23(6.0)	
	UBUDEHE 2	4(1.0)	87(22.7)	0.205
	UBUDEHE 3	3(0.8)	264(68.8)	
	UBUDEHE 4	0(0.0)	3(0.8)	
Employment				
	Unemployed	0(0.0)	47(12.2)	
	Farmer	6(1.6)	237(61.7)	
	Self-Employed	0(0.0)	64(16.7)	0.489
	Employed	0(0.0)	9(2.3)	
	Retired	1(0.3)	16(4.2)	
	Student	0(0.0)	4(1.0)	
Education Level				
	No education	1(0.3)	91(23.7)	
	Primary	3(0.8)	211(54.9)	0.321
	Higher Education	3(0.8)	75(19.5)	
Health insurance				

Insured	7(1.8)	371(96.6)	**0.000**
Non-insured	0(0.0)	6(1.6)	
Tobacco smoking			
Yes	0(0.0)	40(10.4)	
No	7(1.8)	337(87.8)	0.46
Atherosclerotic Cardiovascular disease			
Yes	4(1.0)	4(1.0)	**0.000**
No	3(0.8)	373(97.1)	
Hypertension			
Yes	6(1.6)	246(64.1)	**0.042**
No	1(0.3)	131(34.1)	
Total Cholesterol			
Normal	222(67.6)	6(1.6)	0.099
High	106(32.3)	0(0.0)	
LDL Cholesterol			
Normal	182(58)	5(1.6)	0.207
High	132(42.0)	1(0.0)	
HDL Cholesterol-Male			
Normal	65(63.7)	3(2.9)	0.593
Low	33(32.3)	1(0.1)	
HDL Cholesterol-Female			
Normal	78(34.36)	1(0.1)	0.576
Low	147(64.7)	1(0.1)	
Triglycerides			
Normal	261(80.5)	5(1.5)	0.707
High	57(17.6)	1(0.3)	

A binary logistic regression was conducted on variables which were significantly associated from bivariate analysis that include gender, health insurance, atherosclerotic cardiovascular disease and hypertension for controlling for confounding and effect modification.

The results presented in table 7 below, all significant variables from bivariate analysis remained significant in binary logistic regression. The results revealed that female patients are 10.3 times more likely not to receive statin than male patients (AOR=10.35, 95% CI: 1.003-46.865, P=0.042).

Non-insured diabetic patients participated in this study were 2.15 times less likely to receive statin (AOR=2.15, 95% CI: 1.001-7.027, P=0.006) than those with insurance scheme. Those without atherosclerotic cardiovascular disease (ASCVD) were 1.602 times less likely to use statin than those with ASCVD (AOR=1.602, 95% CI: 1.102 - 4.219, P=0.008). Patients without hypertension were 2.41times likely not to use statin than those with hypertension (AOR=2.41, 95% CI: 1.023-8.206, P=0.031).

Table 7:Multivariate analysis of factors associated with no statin use among diabetic patients

Variables	Description	AOR	95% CI		P-Value
			Lower	Upper	
Gender					
	Male	10.35	1.003	46.865	**0.042**
	Female	Ref			
Health insurance					
	Insured	2.15	1.001	7.027	**0.006**
	Non-insured	Ref			
Atherosclerotic Cardiovascular disease					
	Yes	1.602	1.002	4.219	**0.008**
	No	Ref			
Hypertension					
	Yes	2.41	1.023	8.206	**0.032**
	No	Ref			

Chapter IV. DISCUSSION

The present study had objectives of assessing the use of statins among diabetic patients aged between 40-75 years old at CHUK, CHUB and RDA Clinic, exploring the association between the level of cardiovascular risk and prescribed statin intensity and the risk factors associated with the use of statin therapy among the diabetic patients of the study group.

Our study revealed that among 384 diabetic patients participated in the study, only 7(1.8% ≈ 2%) received statin therapy as a primary or secondary prevention for cardiovascular diseases. There is paucity of research on prevalence of statin use in Rwanda. The study conducted on 1427 patients with T2DM and 159 stroke survivors encountered at 5 hospitals in Ghana found that 16.8% of patients were on statins for primary prevention (25). The prevalence of statin prescription for primary prevention of ASCVD was also found low in a study conducted in Quatar on 23934 T2DM patients, where 66% received statins at least once during 2019 (26).

This may be related to patients or physician inertia, or lack of local guidelines on ASCVD prevention in diabetics patients, research on why statin under prescription, are encouraged.

The study revealed among 7 (2%) patients who used statin as prevention for cardiovascular disease, 4(57.1%) were on atorvastatin, 2(28.6%) were on rosuvastatin, and 1(14.3%) were on simvastatin. This conforms with the study conducted on 1427 patients with T2DM in Ghana found that more patients (86.7%) were on atorvastatin followed by rosuvastatin (10.0%), (25).

In this study, 3 of 7 (42.8%) diabetic patients used statin as primary prevention for cardiovascular disease compared to 4(57.2%) on statin as secondary prevention. This is in line with the study conducted by Berthold et al.,(2009) who found that the prescription of statins was significantly higher in the secondary as compared to primary prevention group(27).

Regarding the factors that influence the poor adherence to statins among diabetic patients, this research found that gender, health insurance, atherosclerotic cardiovascular disease and hypertension remained significantly associated with uptake of statins in multivariate analysis. The results showed that among diabetic patients, the low prescription of statins was high in female patients 266(69.3%) comparing to males 111(28.9%) and so, gender was significantly associated with uptake of statins ($p=0.028$), female patients were 10.35times more likely not to use statin dose than men. This was found also by the research conducted by Gupta et al., (2016) found gender was significantly associated with statin uptake ($p<0.001$) and that adherence was lower in women (52.1%) compared to men (57.2%) (28). Another study by Daban et al., (2022) showed that males are 1.2times more likely to use statin compared to women(26).

Non-hypertensive patients were found to be 2.4 times less likely to use statins compared to those who are hypertensive ($p=0.042$), 6 of 7 patients who used statins had hypertension. This was

highlighted in the study conducted by Daban et al., (2022) which also found that diabetic patients with hypertension were 1.51 times more likely to use statins(26). Another study conducted in Ghana by Sarfo & Ovbiagele, (2020) showed that T2DM patients with hypertension were 1.8 times more likely to use statin for primary prevention of CVD(25). The study conducted in Malaysian by Baharudin et al., (2022) in Malaysia found that patients with hypertension are 2.8 times more likely to take lipid-lowering medications than those who are not hypertensive.

During this study, having health insurance was found associated with being on statins. and all diabetic patients on statins were insured. Having no insurance increased 2.15 times chance of not using the statins compared to insured patients.

This was also found in a study conducted in Tanzania by Bideberi and al. on statin prescription patterns and associated factors among patients with type 2 diabetes, they found that having health insurance was strongly associated with using statins for prevention of cardiovascular disease, patients without health insurance were 0.056 less likely to use statins for prevention.

Study limitations

The main drawback of our study was the small number of participants who were taking statins, which limited our ability to analyze the risk variables for these participants.

The study was only carried out at three locations; other locations, including district hospitals, should be used in future research to ensure national generalizability.

CHAPTER V: CONCLUSION

V.0 Introduction

This chapter presents the summary of findings, conclusion and recommendations according to research findings.

V.1 Conclusion

Despite well-documented benefits, statins are underused. A large proportion of diabetic patients in the study are not receiving statins. Only 7(≈2%) were on statins. The statin use was higher among males, insured patients, having ASCVD and patients with hypertension. The higher the risk level of ASCVD, the higher statin intensity was received by patients prescribed on statins. The findings call for improvement in diabetes quality of care by implementing evidence-based guideline recommendations.

V.2 Recommendation

To the government

- Improving awareness on therapeutic targets particularly on adherence to statins prescription may significantly increase the number of diabetic patients receiving statins. Radio talks, Public posters, reading manuals etc. may help to communicate the benefits of statin use for diabetic patients.
- To avail statins medications to the public hospitals where, they can be covered by community based health insurance.

To the community

- Poor adherence to statins can lead to worse health outcomes, including cardiovascular disease-related emergencies, hospitalizations, medical costs, and even death. It has been shown that the majority of people with diabetes in the community do not achieve established goals for optimal glycemic, lipid, and blood pressure control and suffer from comorbidities and polypharmacy. This failure to attain therapeutic targets is worrisome and should be improved through peer education and mobilization

To physician

- This study should awaken our attention on compliance to the guidelines on beneficial effect of statin in diabetic patients. To keep doctors informed on the prevention of atherosclerotic vascular diseases in diabetics, hospitals should increase the number of presentations on diabetes standard of care.

To future researchers

- This research was conducted on three Health care facilities, CHUK, CHUB and RDA clinic. There is a need of research than can cover more Health facilities to identify the challenges for a poor adherence of statins. Further studies are also needed to analyze the

clinical gap between the guidelines and practice of statins prescription among diabetic patients.

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APPENDIX

TIMETABLE

Proposal writing and submission	**1-2/2022**
Enrollment	**3-5/2022**
Preliminary Data analysis	**5/2022**
Faculty presentation(provisional data)	**6/2022**
Collections/ Modifications	**7/2022**
Submission for Publication	**7/2022**
Final Draft Preparation	**8/2022**

BUDGET

	Item	Quantity	Unit price .frw	Total price .frw
1.	Printing of questionnaires and consent forms	400 copies	100	400000
2.	Communication expenses (3G monthy data)	3 months	25000	75000
3.	Transportation costs to study site: from Kigali to Huye (CHUB)	121km	700	254100
	To CHUK	0	700	0
	To Rwanda diabetic association clinic	0	700	0
4.	Statistical data analysis	1	350000	350000
5.	Draft printing	5 copies	2500	12500
6.	Final printing	10 copies	2500	25000
7.	Book binding	15 copies	5000	75000
8.	Sub total			831600
9.	Miscellaneous 15%			124740
	Total :			956340

STATIN THERAPY AMONG DIABETIC PATIENTS IN RWANDA.

QUESTIONNAIRE

1. Name initial:
2. Study site:
3. Study number:
4. Date of birth/ Age:
5. Gender:
6. Residence: District:
7. Marital status: Never married○ Married/living together○ Divorced/separated/widowed○
8. Ubudehe category: I II III IV
9. Employment status:
10. Level of education: No education○ Primary school ○ secondary school or higher ○
11. Health Insurance: Yes ○ No ○ If yes, specify:
12. Diabetes type:type 1 ○ Type 2 ○
13. BMI(kg/m2):
14. Tobacco smoking: yes ○ no ○
15. Atherosclerotic vascular diseases: yes ○ No ○
16. If yes on 15th question: ischemic heart diseases ○ stroke ○ PAD ○ abdominal aneurysm ○
17. .Total cholesterol:
18. LDL C:
19. TRIGLYCERIDES:
20. HDL:
21. BP:
22. HTN: yes ○ No ○
23. ASCVD score:
24. ASCVD score: Low risk ○
    Borderline low ○
    Moderate risk ○
    High risk ○

prescribing pattern of statins among diabetics

statins: yes ○ no ○

1.atorvastatin: 40-80 mg ○ 10-20mg ○ 5mg ○

2. Rosuvastatin:20-40mg ○ 5-10 mg ○

3. Lovastatin:40 mg ○ 20mg ○

4. Simvastatin: 20-40mg ○ 10 mg ○

Thank you for completing these questions

IBIBAZO KU BUSHAKASHATSI KU MITI IGABANYA IBYAGO BYO KUGIRA INDWARA Z`IMITSI N`UMUTIMA MU BARWAYI BA DIYABETE.

1. Amazina:
2. Aho ubushakashatsi bubera:
3. Nimero:
4. Imyaka:
5. Igitsina:
6. Aho atuye: akarere: Umurenge: akagali:
7. Irangamimirere: Ingaragu○ Arubatse/ barabana○ baratandukanye/ yarapfakaye○
8. Ikiciro cyubudehe : I ○ II○ III ○ IV ○
9. Imirimo akora:
10. Amashuri yize: ntiwize○ amashuri abanza○ amashuri yisumbuye/ n'ayisumbuyeho○
11. Ufite ubwishingizi mu kwivuza: yego○ oya○ niba ari yego, ubuhe:……
12. uburwayi bwa diyabete:ubwoko bwa 1 ○ ubwoko bwa 2 ○
13. Ingano yawe (BMI):
14. Unywa itabi: yego ○ oya ○
15. Uburwayi bw`umutima n`imitsi buterwa n`ibinure: yego ○ oya ○
16. Niba ari yego kukibazo cya 15 n`ubuhe burwayi: stroke ○uburwayi bw`umutima○uburwayi bw`imitsi○uburwayi bw`umutsi wo mu nda wabyimbye○
17. ingano ya cholesterol mu maraso○
18. ingano ya cholesterol ya LDL:
19. :ingano ya cholesterol ya HDL :
20. Ingano ya triglycerides:
21. ibipimo by`umuvuduko w`amaraso:
22. mufite uburwayi bw`umuvuduko w`amaraso: yego ○ oya ○
23. igipimo cyo kugira ibyago byo kugira indwara z`imitsi n`umutima mugihe cy`imyaka icumi:
24. ibyago byo kugira indwara z`imitsi n`umutima mugihe cy`imyaka icumi:
    -ikigero cyo hasi:
    -ikigero cyegereye icyo hasi:
    -ikigero kiringaniye:
    -ikigero cyo hejuru:

Imiti igabanya ibinure ufata

imiti igabanya ingano y`ibinure: yego ○ oya○

1.atorvastatin:40-80 mg○ 10-20 mg○ 5mg○

2.rosuvastatin :20-40 mg ○ 5-10 mg ○

3.lovastatin:40 mg○ 20mg○

4.simvastatin:20-40 mg○ 10 mg○

Murakoze kwitabira ubushakashatsi.

INFORMED CONSENT FORM FOR ANALYSIS OF STATIN PRESCRIPTION AMONG ADULTS DIABETICS PATIENTS IN RWANDA.

This consent form is for those who are invited to participate in our study on "**STATIN THERAPY AMONG DIABETICS PATIENTS IN RWANDA.** Meaning finding out the prevalence of statin prescription among diabetic patients between 40 -75 years.

This form comprises of two sections:

1. Introduction to the study.
2. Consent form.

SECTION I: **Introduction to the study:**

We are going to explain and invite you to participate in this study. You will think about it and ask questions if necessary so that you understand the whole process, benefits and possible risks (although there are no expected risks) before you decide to accept to participate in this study.

My name is **KWITONDA Cedric**, a medical doctor by profession I'm also a fourth year student in Internal medicine specialization program (master's degree) at University of Rwanda college of medicine and health sciences. We are carrying out a research on statins therapy among diabetics patient at Butare University Teaching Hospital, Kigali University Teaching Hospital, Rwanda diabetic association clinic so that we can improve to standard of care of diabetics patients.

Objective of the study:

The aim of this study is to assess statin therapy among diabetics and to analysis the cardiovascular risk in those patients.

Methods of the study intervention:

Our study will involve using a questionnaire, which will be given to participants to fill in their demographics and problems related to their illnesses including comorbidities, medications they are prescribed. Which at the end will be put- together and analyzed to know the magnitude and characteristics of all patients and that will help us to make an appropriate conclusion.

Participant selection:

We invited all diabetics patient of 40 -75 years age group attending IM OPD clinic at 2 referral hospitals: KUTH, BTUH and RWANDA diabetic association clinic

Right to participation:

Your participation in this study is fully voluntary. You will continue to get same management as you have been receiving even if you choose not to participate. You are allowed to stop your participation even during the process of the study. This will not affect in anyway your deserved management.

Duration of study:

This study will last for 3 months period. Survey questionnaire filling will take not more than 20 minutes. It will not delay your treatment schedules.

Risks:
This study is entirely safe there is no expected risks.

Benefits and reimbursement:

There is no reimbursement for any one's participation in this study.

Confidentiality:

The information that will be recorded from your charts or collected from you, will be highly confidential. This information will be stored on a secured file in our password protected computer. Our questionnaire files have not included a NAME to protect the participant and only the researchers will have access to them.

Sharing the results:

We plan to publish the results for academic and research purposes and we shall feed back to the treatment team for self-evaluation, your confidentiality will always be protected throughout.

CONTACTS:
Door for questions is always open and in case you can contact the following:

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CMHS IRB Chair Person: +250788490522.

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Mr. Emmanuel Munyaneza, BScN, MSc Postgraduate Coordinator and Secretary of Research and Ethics Committees at CHUK Tel: +250788213765 Email: emamunyaneza@gmail.com

SECTION II**: consent form.**

I have read and understood information provided or read to me above, all my questions have been answered to my satisfaction. I consent voluntarily to participate in this study.

Printed name of participant :…….

Signature of participant:…….

Dates: ……..

If illiterate

I have witnessed the accurate reading of study information and consent form to the potential participant, and the individual has had chance to ask questions and obtain satisfying responses. I confirm that the individual has given consent freely.

Printed names of witness: …….

Signature of witness:…….

thumb print of participant:……..

Dates :…….

Statement by the researcher/individual obtaining consent:

I have accurately read out the information sheet to the potential participant, and made sure that the participant understands the above information to my best of ability.

I confirm that the participant was given opportunity to ask questions about the study, and all the questions have been answered correctly to best of my knowledge.

I confirm that the individual has not been forced into giving consent, and the consent has been given freely.

A copy of this consent form has been provided to the participant.

Print name of Researcher/ person obtaining consent:…….

Signature of Researcher/ person obtaining consent:……

Dates :…….

INYANDIKA NSABA BURENGANZIRA MU KWITABIRA UBUSHAKASHATSI

Iyi nyandiko nsabira uruhushya igenewe abantu bose batumiwe kwitabira ubu bushakashatsi " kurebera hamwe ikigero cy`imiti igabanya ibinure mu barwayi ba diyabete mu Rwanda mu bitaro bikuru byo mu Rwanda".

Iyi nyandiko igizwe n'ibice bibiri:

1.**Iriburiro kubushakashatsi.**

2.**Inyemeza ruhushya**.

IGICE I: Iriburiro kubushakashatsi:

Tugiye kubasobanurira tunabahamagarire kwitabira ubu bushakashatsi. Mbere yogufata ikimezo musabwe kubitekerezaho mukanabaza ibibazo byose mwifuza kugirango murusheho gusobanukira uko ubu bushakashatsi buzakorwa n'ingaruka (nubwo ntazo) mwahura nazo mugihe mwaba mwemeye kwitabira.

Amazina yanjye ni: **KWITONDA Cedric**, umuganga wabigize umwuga nkaba ndi mumwaka wa kane wikiciro cyagatatu cyakaminuza aho nitoza kuba inzobere mundwara z'umubiri muri kaminuza nkuru y'uRwanda ishami ry'ubuzima. Tukaba turimo gukora ubushakashatsi ku byerekeye imiti igabanya ibyago byo kugira indwara z`umutima n`imitsi mu barwayi ba diyabete mu bikuru byo mu Rwanda mu kunoza imitangire y'ubu buvuzi.

Intego yubu bushakashatsi:

Indwara ya diyabete nimwe mu ndwara zongera ibyago byo kurwara umutima n`imitsi.kubera ibyo byago biterwa na diyabete ningombwa guhabwa ubuvuzi bugabanya ibyo byago mubarwayi ba diyabete bari hagati y`imyaka 40-75.ubu bushakashatsi bugamije kumenya uburyo abarwayi ba diyabete murwanda bahabwa iyo miti no kumenya ibyago bafite byo kugira indwara z`umutima n`imitsi

Uburyo ubu bushakashatsi buzakorwamo:

Muri ubu bushakashatsi tuzifashisha urupapuro nkusanyamakuru, aho ruzahabwa abitabiriye ubushakashatsi kugirango buzuzemo ibisubizo byose bizaba biriho.hanyuma bikazashirwa hamwe hakurwamo umwanzuro kuntego zubushakashatsi.

Ihitwamo ryabazitabira:

Abarwayi bavurwa bataha barwaye diyabete bari mu kigero cy`imyaka hagati ya 40 na 75 mubitaro bibiri bikuru byo mu Rwanda aribyo CHUK, CHUB na clinic y`urugaga rw`abarwayi ba diyabete mu Rwanda.

Uburenganzira bwo kwitabira:

Kwitabira muri ubu bushakashatsi ni ubushake. Ndetse wemerewe guhagarika kwitabira mo hagati mubushakashatsi igihe icyo aricyo cyose. Ibi ntibishobora kubangamira cyangwa kugira ingaruka izo arizo zose kubuvuzi bwawe usanzwe uhabwa.

Igihe ubushakashatsi buzamara:

Ubu bushakashatsi buzamara igihe kigera kumezi 2; naho kuzuza urupapuro nkusanyamakuru bizajya bitwara iminota itarenze 20 bitabangamiye gahunda zindi zubuvuzi bukorerwa umurwayi.

Ingaruka zava muri ubu bushakashatsi:

Ntangaruka nimwe bizatera umurwayi kwitabira ubu bushakashatsi.

Ibihembo:

Nta bihembo biteganyirijwe uwo ariwe wese uzitabira ubu bushakashatsi.

Kubika ibanga:

Amakuru yose yerekeranye nubu bushakashatsi abikwa mwibanga rikomeye. Amakuru azajya abikwa kuri zamudasobwa zirinzwe numubare w'ibanga uzwi nabashinzwe ubu bushakashatsi gusa. Ikindi ntamazina bwite yumurwayi azagaragara kurupapuro nkusanyamakuru muburyo bwo kurinda ibanga .

Gutangaza ibyavuye mubushakashatsi:

Duteganya gutangaza ibizava muri ubu bushakashatsi kumpamvu z'imyigire n'ubushakashatsi. Tuzanamenyesha imyanzuro yavuyemo ikipe y'ubuvuzi murwego rwo kurushaho kunoza imitangire y'ubu buvuzi.

Mwaduhamagara:

Mushobora kuduhamagara igihe icyo aricyo cyose tukabaha ubusobanuro burambuye kurushaho.

KWITONDA Cedric: +250788833205, kicedi19@yahoo.com.

Amha Mesesha:+250787662235,amha.mesesha@kfhkigali.com

MULIMA Yves:+250788774914,mulimayves@gmail.com

UMUYOBOZIUMUKURU W'UBUSHAKASHATSI MURI KAMINUZA Y'URWANDA: Tel +250788490522.

UMUYOBOZI MUKURU WUNGIRIJE W'UBUSHAKASHATSI MURI KAMINUZA Y'URWANDA: Tel +250783340040.

Mr Emmanuel Munyaneza,umuhuzabikorwa w`icyiciro cya gatatu mu ishami ry`ubuganga,umunyamabanga wa Research and Ethics Committees kuri CHUK

Tel: +250788213765 Email: emamunyaneza@gmail.com

Igice cya II:Amasezerano yo kwemera gukorerwaho ubushakashatsi:

Maze gusoma ibyanditse hejuru kandi nabisobanukiwe. Nasobanuriwe birambuye mu rurimi numva intego, inyungu n'ingaruka muri ubu bushakashatsi. Nasobanuriwe kandi ko nemerewe kwivana mu mubare w'abakorerwaho ubushakashatsi igihe mbishakiye ntangaruka ngize.

Nshyize umukono kuri aya masezerano nsobanukiwe kandi nemerako nkorerwaho/umurwayi wanjye akorerwaho ubushakashatsi.

Nyewe Umurwayi.. / umurwaza ……. Nsinye nk'ikimenyetso cyuko nemeye kugira uruhare muri ubu bushakashatsi.

Umukono wanjye / umurwaza ……Itariki: ……

Nasobanuriye umurwayi/umurwaza mu buryo burambuye intego, inyungu n'ingaruka by'ubu bushakashatsi.

Umushakashatsi: ……. Itariki :……

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 9th /March /2022

Dr KWITONDA Cedric
School of Medicine and Pharmacy CMHS, UR

Approval Notice: No 190/CMHS IRB/2022

Your Project Title ***"Statin Therapy Among Diabetic Patients In Rwanda"Cross Sectional Study"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason) Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Stefan Jansen	UR-CMHS			X
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		X	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Prof Gishoma Darius	UR-CMHS	X		
Prof Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 7th March 2022, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

Email: researchcenter@ur.ac.rw P.O Box 3286 Kigali, Rwanda www.ur.ac.rw

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

CLINICAL EDUCATION AND RESEARCH DIVISION
RESEARCH DIRECTORATE
ETHICS COMMITTEE **Huye, April 27, 2022**

Approval Notice: No: REC/UTHB/104/2022

Dr Cedrick KWITONDA
Email: kicedi19@yahoo.fr
Tel. +250 788833205

Reference is made to your letter requesting for data collection approval of your study entitled **"Statin Therapy among Diabetic Patient in Rwanda, Baseline study"**

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance and should be conducted within University Teaching Hospital of Butare.

Please note that approval of the protocol and consent form is valid for one year starting on the issue date and shall be renewed on request. You are responsible to fulfilling the following requirements:

- Changes, amendments and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes
- Only approved consent forms are to be used in the enrollment of participants
- All consent forms signed by subjects should be retained on file. The committee may conduct audits of all study records. Consent documentation may be part of such audits
- A continuing review application must be submitted to the committee in a timely fashion and before expiry of this approval
- Failure to submit continuing review application will result in termination of the study
- Notify the committee once the study is finished
- Identification of participants must be kept confidential for the duration of the study.

Sincerely

Dr. HABIMANA Emmanuel
Chairperson of Ethics Committee/CHUB

Digitally signed by HABIMANA Emmanuel
Date: 2022.04.28 17:04:26 +02'00'

Cc:

- ✓ Director General
- ✓ Head of Clinical Education and Research Division
- ✓ Director of Research
- ✓ Research officer
- ✓ Head of Intern Medicine Department

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

22nd Apr,2022 Ref.:EC/CHUK/066/2022

Review Approval Notice

Dear KWITONDA Cedric,

Your research project: ***"statin therapy among diabetic patient in Rwanda "***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 22nd Apr,2022 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:www.chuk.rw/research/fullreport/?appid=566&&chuk.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

Dr Emmanuel Rusingiza Kamanzi
The Chairperson, Ethics Committee,
University Teaching Hospital of Kigali

ETHICS COMMITTEE
CHUK

Scan code to verify.

" University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations "