### Comparison of various Cardiovascular risk scores to assess cardiovascular risk in people living with HIV on HAART in Kasturba Hospital Manipal.

A Project Report Submitted To MANIPAL ACADEMY OF HIGHER EDUCATION In partial fulfillment for the degree of Master of Pharmacy (M.Pharm)





(Deemed to be University under Section 3 of the UGC Act, 1956)

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### April 2019



(A constituent unit of MAHE, Manipal)

### CERTIFICATE

This is to certify that the research work embodied in the dissertation titled "Comparison of various Cardiovascular risk scores to assess cardiovascular risk in people living with HIV on HAART in Kasturba Hospital Manipal." submitted in partial fulfillment for award of Master of Pharmacy comprises bonafide work done by Ms. Kruthiventi Bhavana (Reg. No. 170608002), in Manipal College of Pharmaceutical Sciences during the academic year 2018-2019 under my supervision and guidance.

I recommend this piece of work for acceptance as a dissertation for the fulfillment of the degree of **Master of Pharmacy** of Manipal Academy of Higher Education for the year 2018-2019.

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I wish her all the best for her future endeavors.

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## DECLARATION

I, Kruthiventi Bhavana, hereby declare that the dissertation work titled "Comparison of various Cardiovascular risk scores to assess cardiovascular risk in people living with HIV on HAART in Kasturba Hospital Manipal." submitted for the award of Master of Pharmacy in Pharmacy Practice degree comprises bonafide research work carried out by me under the supervision and guidance of Dr.R.Rajesh, Assistant Professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, and co-guide Dr.Muralidhar Varma D, Associate Professor, Department of General Medicine, Kasturba Hospital, Manipal.

I also declare that the same has not been previously submitted for the award of any degree, diploma or fellowship of this or any other university or institution. The particulars given in this dissertation are true to the best of my knowledge.

SPIRED BY VIE

-Kruthiventi Bhavana

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# ABSTRACT

### ABSTRACT

### **INTRODUCTION:**

The risk of cardiovascular diseases in people living with HIV is greater than in normal individuals

### **OBJECTIVES:**

- 1. To Assess the cardiovascular risks in people living with HIV with HAART using standard cardiovascular risk scores.
- 2. To compare the pattern of cardiovascular disease risk associated with HIV seropositive patients with HAART.

### **METHODOLOGY:**

Patients diagnosed with HIV with HAART with one or other cardiovascular diseases will be enrolled. The data related to various cardiovascular diseases, the duration of cardiovascular disease with onset of HIV infection with HAART. The enrolled patients will be evaluated by using various validated cardiovascular risk scores like the Framingham risk score, American College of Cardiology/American heart association (ACC/AHA) risk score, the Second manifestations of arterial disease (SMART) risk scores. The outcome of the result scores will be compared between the various scores and risk will be categorized. The pattern of cardiovascular risk with its incidence will be reported.

### **RESULTS:**

When the results of the Framingham score was compared with that of the AHA score the kappa coefficient value obtained was 0.282 which shows a fair agreement (0.21 - 0.40) between these two scores. In a similar way, the results of SMART score was compared with that of AHA score, the kappa coefficient value was 0.597 which shows a moderate agreement (0.41 - 0.60) between the scores. And when the results of the Framingham score were compared with SMART score the kappa coefficient value was 0.250 which shows a fair agreement (0.21 - 0.40) between the scores.

### CONCLUSION:

ACC/AHA score is the most commonly used score for cv risk scoring India, and when it was compared with Framingham and SMART score showed fair to moderate agreement concluding that these scores can also be used in addition to AHA score for calculating cv risk scores in India.

### LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome		
HIV	Human Immunodeficiency Virus		
HAART	Highly Active Anti- retroviral Therapy		
PI	Protease Inhibitor		
NRTI	Nucleoside Reverse Transcriptase Inhibitors		
NNRTI	Non- Nucleoside Reverse Transcriptase Inhibitors		
PLW	People Living With		
OIs	Opportunistic Infection		
WHO	World Health Organization		
ART	Anti-retroviral therapy		
CD4	Cluster of Differentiation		
SPP	Sero positive patients		
ICRF	Individual Case Report Form		
ACC/AHA	American College of Cardiology/American heart association		
SMART	Second manifestations of arterial disease		
FRS	Framingham risk score		

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### 1. INTRODUCTION:

Human immunodeficiency virus (HIV)/ Acquired immunodeficiency syndrome (AIDS) is a chronic illness. Around the world, approximately 36.9 million people are currently living with HIV/AIDS, of these around 1.8 million children (<15 years) are infected by HIV positive mother during pregnancy, childbirth or breastfeeding. In 2004 approximately 1.9 million people living with HIV were accessing treatment through highly active antiretroviral therapy (HAART) which is a combination of two nucleoside reverse transcriptase inhibitors (NRTI), a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor (NNRTI), with an increase of 1.4 million people in 2010 and 8 million in 2016 and 21.7 million in 2017. AIDS-related deaths have been lowered by more than 51% since 2004. In 2017, 940 000 people have died from AIDS compared to 1.4 million in 2010 and 1.9 million in 2004 respectively.

People living with HIV (PLW-HIV) are living long enough to experience non-AIDS related illness. This includes chronic obstructive pulmonary disorder, diabetes, kidney diseases, hypertension, cardiovascular diseases(CVD) and cancer. CVD a commonly used term for diseases of the heart and blood vessels is the number one cause of death worldwide. It is projected that annual global cardiovascular deaths will increase from 16.7 million in 2002 to 23.9 million by 2030. Furthermore, the estimated risk of cardiovascular diseases in PLW-HIV is 61% more.

The advent of HAART has been associated with a profound reduction in morbidity and mortality from HIV/AIDS. However, several reports have documented the increased prevalence of CVD risk factors (such as obesity, elevated blood pressure, elevated blood sugar, hypertriglyceridemia, and low high-density

lipoprotein cholesterol (HDL-c)) in both HAART-treated and HAART-naïve patients.

The occurrence of non-AIDS-related morbidities might be higher in PLW-HIV than in the general population for three main reasons. First, the HIV-positive population in high-income settings has a high level of traditional risk factors for non-AIDS morbidities, such as smoking and hepatitis, co-infection. Second, available evidence suggests that the persistent immunodeficiency, immune dysregulation, immune activation, and inflammation associated with HIV infection, including patients on ART, might increase the risk of some of these morbidities. Third, antiretroviral-related adverse events such as dyslipidemia and diabetes might also play a part.

Immune dysfunction and persistent inflammation features of HIV infection have a possible role in the pathogenesis of CVD risk in addition to traditional risk factors such as cigarette smoking, elevated blood pressure, and total cholesterol.

WHO recommends that the assessment and management of CVD should be provided for all PLW-HIV. There are various risk estimators to calculate the risk of developing cardiovascular diseases in people such as Framingham risk score(FRS), American college of cardiology/American heart association (ACC/AHA) risk estimator, Second manifestations of arterial disease (SMART) risk score<sup>(1)</sup>.

American College of Cardiology/American Heart Association (ACC/AHA) is the most commonly used risk score for estimating the cardiovascular risk in India. However, the best score for estimating the risk of cardiovascular diseases is unknown. There are no studies performed in PLW-HIV to estimate cardiovascular risk in India. Therefore, this study was to assess the CVD risk scores in PLW-HIV

who are on HAART and to assess for the possible risk related to CVD using three different CVD risk scores.



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### 2. REVIEW OF LITERATURE:

The aim of this study was to compare the predictions of Framingham cardiovascular (CV) risk score (FRS) and the American College of Cardiology/American Heart Association (ACC/AHA) risk score in an HIV outpatient clinic in the city of Vitoria, Espirito Santo, Brazil. In a cross-sectional study 341, HIV infected patients over 40 years old consecutively recruited were interviewed. Cohen's kappa coefficient was used to assess agreement between the two algorithms. 61.3% were stratified as low risk by Framingham score, compared with 54% by ACC/AHA score (Spearman correlation 0.845; p < 0.000). Only 26.1% were classified as cardiovascular high risk by Framingham compared to 46% by ACC/AHA score (Kappa = 0.745; p < 0.039). Only one out of eight patients had a cardiovascular high risk by Framingham at the time of a myocardial infarction event registered up to five years before the study period. Both cardiovascular risk scores but especially Framingham underestimated high-risk patients in this HIV-infected population<sup>(1)</sup>.

This study used a mathematical model to project cumulative CVD incidence. They simulated a male and female cohort for each of 3 populations: US general population; HIV-uninfected, at high risk for HIV; and PLWH and incorporated the higher smoking prevalence and increased CVD risk due to smoking into the HIV-infected and HIV-uninfected, at high risk for HIV populations. They incorporated HIV-attributable CVD risk, independent of smoking. For men, life expectancy ranged from 70.2 to 77.5 years and for women from 67.0 to 81.1 years (PLWH, US general population). Without antiretroviral therapy, lifetime CVD risk for HIV-infected males and females was 12.9% and 9.0%. For males, by age 60, cumulative CVD incidence was estimated at 20.5% in PLWH in care, 14.6% in HIV-uninfected high-risk persons, and 12.8% in the US general population. For females, cumulative

CVD incidence was projected to be 13.8% in PLWH in care, 9.7% for high-risk HIV-uninfected persons, and 9.4% in the US general population. Lifetime CVD risk was 64.8% for HIV-infected males compared to 54.8% for males in the US general population, but similar among females <sup>(2)</sup>.

This was a cross-sectional study of HIV-positive patients attending the Lagos University Teaching Hospital, Nigeria. Anthropometric and blood pressure measurements were performed; fasting lipid profile, plasma glucose, homocysteine, and hsCRP were determined, as well as prevalences and risk assessments. Statistical tests were used to compare the groups and p-value <0.05 was considered to be significant. 283 subjects were recruited for this study (100 HIV-positive treatmentnaive, 100 HIV-positive treated and 83 HIV negative controls). Compared to the controls, mean (sd) values were significantly higher among HIV-treated subjects: waist circumference=88.7 (10.4), p=0.035; systolic bp= 124.9 (20.7), p=0.014; glucose= 5.54 (1.7), p=0.015; triglyceride= 2.0 (1.2), p<0.001; homocysteine= 10.9 (8.9-16.2), p=0.0003; while hsCRP= 2.9 (1.4-11.6), p=0.002 and HDL-C=0.9 (0.4), p=<0.0001 were higher among the HIV-naive subjects. Likewise, higher prevalence of the risk factors was noted among the HIV-treated subjects except low HDL-C (p<0.001) and hsCRP (p=0.03) which were higher in the HIV naive group. Risk assessment using ratios showed a high risk for CVD, especially in the HIV-naive group. The median range for Framingham risk assessment was  $1.0 - 7.5\%^{(3)}$ .

This study was a systematic review and meta-analysis of studies from the peerreviewed literature. Eligible studies were observational and randomized controlled trials, reporting CVD, defined as myocardial infarction (MI), ischemic heart disease, cardiovascular and cerebrovascular events or coronary heart disease among HIVpositive adults. Pooled relative risks were calculated for various groupings, including different classes of antiretroviral therapy (ART). The relative risk of CVD

was 1.61 [95% confidence interval (CI) 1.43–1.81] among PLWHIV without ART compared with HIV-uninfected people. The relative risk of CVD was 2.00 (95% CI 1.70–2.37) among PLHIV on ART compared with HIV-uninfected people and 1.52 (95% CI 1.35–1.70) compared with treatment-naïve PLWHIV. We estimate the relative risk of CVD associated with protease inhibitor (PI), nucleoside reverse transcriptase inhibitor- and nonnucleoside reverse transcriptase inhibitor-based ART to be 1.11 (95% CI 1.05–1.17), 1.05 (95% CI 1.01–1.10) and 1.04 (95% CI 0.99–1.09) per year of exposure, respectively. Not all ART was associated with increased risk; specifically, lopinavir/ritonavir and abacavir were associated with the greater risk and the relative risk of MI for PI-based versus non-PI-based ART was 1.41 (95% CI 1.20–1.65)<sup>(4)</sup>.

This was a cross-sectional study. Adults with HIV infection were studied. Demographic, clinical and anthropometric data, serum glucose and lipids were obtained. Cardiovascular risk was calculated through the Framingham risk score (FRS) and CACS. Categorical variables were compared by Chi-square or Fisher's exact test, and continuous variables were analyzed by Student *t* test or Mann-Whitney test. An analysis of concordance between FRS and CACS was performed using the kappa statistic. Forty patients aged 45.9 } 8.1 years, were studied. Age of risk for CAD were found in 30.0%, hypertension in 55.0%, diabetes in 10.0%, smoking in 35.0%, dyslipidemia in 67.5% and family history of CAD in 57.5%. Altered levels of total cholesterol, LDL-cholesterol, HDL-cholesterol, and triglycerides were found in 30.0%, 25.0%, and 82.5%, respectively. HDL-cholesterol and triglycerides were altered more frequently among protease inhibitors users. The FRS classified the risk as low for 72.5%, moderate for 25.0%, and high for 2.5%. CACS > 0 was found in 32.5% of the patients, in 67.5% the score was low,

in 17.5% moderate, and in 15.0% high. Concordance between FRS and CACS showed a kappa =  $0.435^{(5)}$ .



## **OBJECTIVES**

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### OBJECTIVES

### **3. OBJECTIVES:**

- 1) To Assess the cardiovascular risks in people living with HIV with HAART using standard cardiovascular risk scores.
- 2) To compare the pattern of cardiovascular disease risk associated with HIV seropositive patients with HAART.



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### 4. METHODOLOGY:

Study Site:

Department of Medicine, Kasturba Hospital, Manipal.

Study duration:

This study was conducted for a period of 6 months. From November 2018 to April 2019.

Ethical Approval:

The protocol for this study was approved by the institutional Ethical Committee of Kasturba Hospital, Manipal.

Study Criteria:

- a) Inclusion criteria:
  - 1) Patients who are above 18 years of age and diagnosed with HIV and who are on HAART with one or other cardiovascular disease.

b) Exclusion criteria:

- 1. Patients with long-term malignancy, renal failure patients and pregnant women will be excluded.
- 2. Patients who are above 18 years of age and diagnosed with HIV and who are not on HAART with one or other cardiovascular disease will be excluded.

Sample size: 141 patients.

Statistical methods: SPSS 20.

Cohen's kappa coefficient is used to assess the agreement between the three cardiovascular risk assessment scores.

### Study procedure:

Patients diagnosed with HIV with HAART with one or other cardiovascular diseases will be enrolled by referring with the medical records between January 2016 to December 2017 from medical records department (MRD) with institutional ethical approval clearance. The data related to various cardiovascular diseases such as Myocardial infarction, angina pectoris, congestive cardiac failure, arrhythmias and other cardiovascular blood vessel disorders will be documented, (like HDL, total cholesterol, SBP, DBP, hypertensive medication, BMI, smoking and alcoholic habits) the duration of cardiovascular disease with onset of HIV infection with HAART. The enrolled patients based on inclusion and exclusion criteria will be evaluated by using various validated cardiovascular risk scores like the Framingham risk score, American College of Cardiology/American heart association (ACC/AHA) risk score, the Second manifestations of arterial disease (SMART) risk scores. The outcome of the result scores will be compared between the various scores and risk will be categorized into low, moderate and severe risk. The data collected will be analyzed using SPSS software, Cohen's kappa coefficient will be used to determine the agreement between the scores.

Cohen's kappa coefficient is the statistical method used to assess the agreement between two different variables, this method will determine the degree of agreement between the variables when compared with each other. Based on the kappa coefficient value the result is categorized into various categories such as poor agreement, slight agreement, fair agreement, moderate agreement, substantial

agreement, and almost perfect agreement. As the coefficient value increases the degree of agreement between the scores also increases.

Outcome measures:

Cardiovascular risk outcomes using various cardiovascular risk scores will be evaluated and reported with its pattern and incidence.

Patients diagnosed with HIV with HAART are enrolled from the MRD.

The data related to various cardiovascular diseases will be documented.

The enrolled patients based on inclusion and exclusion criteria will be evaluated by using various cardiovascular risk scores.

The outcome of the result scores will be compared between the various scores and risk will be categorized.

The scores obtained by the three scores will be compared and assessed by cohen's kappa coefficient.



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Table-1 : Demographic Details Of HIV Patients For Cardiovascular Risk Scores
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CHARACTERISTICS		ACC/AHA SCORE N=141(%)	FRAMINGHAM SCORE N=133(%)	SMART SCORE N=90(%)
Gender	Male	108(76.6)	102(76.6)	75(83.3)
	Female	33(23.4)	31(23.3)	15(16.7)
Age In Years.	20-39	53(37.6)	45(33.8)	2(2.2)
	40-59	84(59.6)	84(63.1)	84(93.3)
	>60	4(2.8)	4(3.0)	4(4.5)
BMI	<19.9	57(40.4)	54(40.6)	39(43.3)
	20-24.9	31(22.0)	29(21.8)	20(22.2)
	>25	10(7.1)	10(7.5)	8(8.9)
	Not Able to Stand	43(30.5)	40(30.0)	23(25.6)
Diet	Vegetarian	2(1.4)	1(0.7)	
	Mixed Diet	139(98.6)	132(99.3)	90(100.0)
Employment Status	Employed	114(80.9)	107(80.5)	79(87.8)
	Unemployed	27(19.1)	26(19.5)	11(12.2)
Alcoholic Habits	Never	123(87.2)	117(87.9)	78(86.6)
	Social	3(2.1)	2(1.5)	2(2.2)
	Habitual	8(5.7)	8(6.0)	5(5.5)
	Reformed	7(5.0)	6(4.5)	5(5.5)
Smoking Habits	Past Smoker	4(2.8)	4(3)	3(3.3)
	Never	129(91.5)	122(91.7)	83(92.2)
	Current Smoker	8(5.7)	7(5.3)	4(4.5)
SBP (Systolic Blood	<120	59(41.8)	57(42.9)	35(38.9)
Pressure)	120-150	78(55.3)	72(54.1)	51(56.6)

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DBP(Diastolic Blood Pressure)	<80	63(44.7)	60(45.1)	39(43.3)
	80-100	78(55.3)	73(54.9)	51(56.7)
Total Cholesterol	50-100	9(6.4)	8(6.0)	5(5.5)
	100-150	67(47.5)	63(47.4)	39(43.3)
	150-200	61(43.3)	59(44.4)	44(48.9)
	>200	4(2.8)	3(3.3)	2(2.2)
HDL	0-30	44(31.2)	41(30.8)	26(28.9)
	30-60	78(55.3)	73(54.9)	49(54.4)
	60-90	19(13.5)	19(14.3)	15(16.7)
Marital Status	Married	114(80.9)	111(83.5)	82(91.1)
	Unmarried	25(17.7)	20(15.0)	6(6.7)
	Divorced	2(1.4)	2(1.5)	2(2.2)
CD4 Cell Count	<=150	90(63.8)	85(63.9)	58(64.4)
	150-300	22(15.6)	20(15.0)	13(14.4)
	300-500	19(13.5)	19(14.3)	11(12.3)
	>500	10(7.1)	9(6.8)	8(8.9)
Hypertensive	Yes	7(5.0)	7(5.3)	7(7.8)
Medication	No	134(95.0)	126(94.7)	83(92.2)

As per Framingham score, the minimum age for calculation of cardiovascular risk is 30 years hence, the patients below 30 years of age were not able to evaluate.

As per SMART risk score, the minimum age for calculation of cardiovascular risk with that score is 40 years hence, the patients below 40 years of age were not able to evaluate.

Out of the 141 patients enrolled, according to ACC/AHA Score majority of them 108 (76.6%) were male and 33 (23.4%) were female. A majority, 84 (59.6%) were in the age group of 40-59 years, followed by 53 (37.6%) patients in the age group of 20-39 years, and least number 4 (2.8%) belong to the age group of >60 years. BMI values showed that 57 (40.4%) falls under the category <19.9, 43 (30.5%) were not able to stand, 31 (22%) are patients between a range of 20-24.9 and 10 (7.1%) falls under >25. Majority patients 139 (98.6%) had mixed diet and 2 (0.4%) had vegetarian diet. Most of the patients were employed 114 (80.9%) and very few 27 (19.1%) were unemployed. Majority of the patients 123 (87.2%) never had alcohol followed by 8 (5.7%) who were habitual alcohol drinkers followed by 7 (5%) who were reformed drinkers, followed by 3 (2.1%) who were social drinkers. Majority of the patients 129 (91.5%) have never smoked, 8 (5.7%) are current smokers and 4 (2.8%) were past smokers. Majority of the patients 78 (55.3%) had systolic blood pressure in the range of 120-150, 59 (41.8%) had <120, 4 (2.8%) had >150. Majority of the patients 78 (55.3%) had diastolic blood pressure in the range of 80-100, followed by 63 (44.7%) who had <80. Majority of the patients 67 (47.5%) had total cholesterol in the range of 100-150, followed by 61 (43.3%) who were in the range of 150-200 and followed by 4 (2.8%) had >200. Most of the patients 78 (55.3%) had HDL in the range of 30-60, followed by 44 (31.2%) who were in the range of 0-30, followed by 19 (13.5%) who had 60-90. Most of the patients 114 (80.9%) were married followed by 25 (17.7%) were single and 2 (1.4%) were divorced. Majority of the patients 90 (63.8%) had a CD4 cell count of  $\leq 150$ , followed by 22 (15.6%) were in the range of 150-300 cells, followed by 19 (13.5%) were in the range of 300-500 cells followed by 10 (7.1%) had more than 500 cells. Majority of the patients 134 (95%) were not on any hypertensive medication, followed by 7 (5%) were on medication.

Out of the 133 patients enrolled, according to Framingham Score majority of them 102 (76.6%) were male and 31 (23.3%) were female. A majority, 84 (63.1%) were in the age group of 40-59 years, followed by 45 (33.8%) patients in the age group of 20-39 years, and least number 4 (3%) belong to the age group of >60 years. BMI values showed that 54 (40.6%) falls under the category <19.9, 40 (30%) were not able to stand, 29 (21.8%) are patients between a range of 20-24.9 and 10 (7.5%) falls under >25. Majority patients 132 (99.3%) had mixed diet and 1 (0.7%) had vegetarian diet. Majority patients were employed 107 (80.4%) and very few 26 (19.5%) were unemployed. Majority of the patients 117 (87.9%) never had alcohol followed by 8 (6%) who were habitual alcohol drinkers followed by 6 (4.5%) who were reformed drinkers, followed by 2 (1.5%) who were social drinkers. Majority of the patients 122 (91.7%) have never smoked, 7 (5.3%) are a current smoker and 4 (3%) were past smokers. Majority of the patients 72 (54.1%) had systolic blood pressure in the range of 120-150, 57 (42.9%) had <120, 4 (3%) had >150. Majority of the patients 73 (54.9%) had diastolic blood pressure in the range of 80-100, followed by 60 (45.1%) who had <80. Majority of the patients 63 (47.4%) had total cholesterol in the range of 100-150, followed by 59 (44.4%) who were in the range of 150-200 and followed by 3 (3.3%) had >200. Majority of the patients 73 (54.9%)had HDL in the range of 30-60, followed by 41 (30.8%) who were in the range of 0-30, followed by 19 (14.3%) who had 60-90. Majority of the patients 111 (83.5%) were married followed by 20 (15%) were single and 2 (1.5%) were divorced. Majority of the patients 85 (63.9%) had a CD4 cell count of <=150, followed by 20 (15%) were in the range of 150-300 cells, followed by 19 (14.3%) were in the range of 300-500 cells followed by 9 (6.8%) had more than 500 cells. Majority of the patients 126 (94.7%) were not on any hypertensive medication, followed by 7 (5.3%) were on medication.

Out of the 90 patients enrolled, according to SMART Score majority of them 75 (83.3%) were male and 15 (16.7%) were female. A majority, 84 (93.3%) were in the age group of 40-59 years, and least number 4 (4.5%) belong to the age group of >60 years. BMI values showed that 39 (43.3%) falls under the category <19.9, 23 (25.6%) were not able to stand, 20 (22.2%) are patients between a range of 20-24.9 and 8 (8.9%) falls under >25. All the patients 90 (100%) had a mixed diet. Majority patients were employed 79 (87.8%) and very few 11 (12.2%) were unemployed. Majority of the patients 78 (86.6%) never had alcohol followed by 5 (5.5%) who were habitual and reformed drinkers, followed by 2 (2.2\%) who were social drinkers. Majority of the patients 83 (92.2%) have never smoked, 4 (4.5%)are a current smoker and 3 (3.3%) were past smokers. Majority of the patients 51 (56.6%) had systolic blood pressure in the range of 120-150, 35 (38.9%) had <120, 4 (4.5%) had >150. Majority of the patients 51 (56.7%) had diastolic blood pressure in the range of 80-100, followed by 39 (43.3%) who had <80. Majority of the patients 39 (43.3%) had total cholesterol in the range of 100-150, followed by 44 (48.9%) who were in the range of 150-200 and followed by 2 (2.2%) had >200. Majority of the patients 49 (54.4%) had HDL in the range of 30-60, followed by 26 (28.9%) who were in the range of 0-30, followed by 15 (16.7%) who had 60-90. Majority of the patients 82 (91.1%) were married followed by 6 (6.7%) were single and 2 (2.2%) were divorced. Majority of the patients 58 (64.4%) had a CD4 cell count of  $\leq 150$ , followed by 13 (14.4%) were in the range of 150-300 cells, followed by 11 (12.3%) were in the range of 300-500 cells followed by 8 (8.9%) had more than 500 cells. Majority of the patients 83 (92.2%) were not on any hypertensive medication, followed by 7 (7.8%) were on medication.

		ACC/AHA SCORE N=141(%)	FRAMINGHAM SCORE N=133(%)	SMART SCORE N=90(%)
Diabetes	YES	14(9.9)	14(10.5)	13(14.4)
	NO	127(90.1)	119(89.5)	77(85.6)
Cerebrovascular Disease	YES	1(0.7)	1(0.7)	-
	NO	140(99.3)	132(99.3)	90(100.0)
Other Cardiovascular	YES	4(2.8)	4(3.0)	3(3.3)
Diseases	NO	137(97.2)	129(97.0)	87(96.7)

Table-2 Co-Morbid Conditions Associated with Cardiovascular Risk Scores

Out of 141 patients enrolled, the co-morbid conditions associated with the cardiovascular risks were diabetes, coronary artery diseases, cerebrovascular diseases, abdominal aortic aneurysm, peripheral artery diseases, and other cardiovascular diseases. Out of which majority people had diabetes 14 (9.9%) followed by other cardiovascular diseases 4 (2.8%) such as, Deep vein thrombosis (DVT) and hypertension followed by cerebrovascular diseases 1 (0.7%).

Out of 133 patients calculated with Framingham score, the co-morbid conditions associated with the cardiovascular risks were diabetes, coronary artery diseases, cerebrovascular diseases, abdominal aortic aneurysm, peripheral artery diseases, and other cardiovascular diseases. Out of which majority people had diabetes 14 (10.5%) followed by other cardiovascular diseases 4 (3%) such as DVT and hypertension, followed by cerebrovascular diseases 1 (0.7%).

Out of 90 patients calculated with SMART score, the co-morbid conditions associated with the cardiovascular risks were diabetes, coronary artery diseases, cerebrovascular diseases, abdominal aortic aneurysm, peripheral artery diseases, and other cardiovascular diseases. Out of which majority people had diabetes 13 (14.4%) followed by other cardiovascular diseases 3 (3.3%).

		ACC/AHA SCORE N=141(%)	FRAMINGHAM SCORE N=133(%)	SMART SCORE N=90(%)
Tuberculosis	YES	108(76.6)	102(76.7)	74(82.2)
	NO	33(23.4)	31(23.3)	16(17.8)
Candidiasis	YES	13(9.2)	11(8.3)	8(8.9)
	NO	128(90.8)	122(91.7)	82(91.1)
Tb Meningitis	YES	7(5.0)	6(4.5)	-
	NO	134(95.0)	127(95.5)	90(100.0)
Pneumocystis pneumonia	YES	1(0.7)	1(0.7)	1(1.1)
	NO	140(99.3)	132(99.3)	89(98.9)
Toxoplasmosis	YES	2(1.4)	2(1.5)	2(2.2)
	NO	139(98.6)	131(98.5)	88(97.8)
Cryptococcal Pneumonia	YES	2(1.4)	2(1.5)	1(1.1)
	NO	139(98.6)	131(98.5)	89(98.9)

Out of 141 patients enrolled 133 people were presented with OIs, most of the OIs was Tuberculosis (TB) 108 (76.6%), followed by 13 (9.2%) candidiasis, 7 (5%) Tb Meningitis, almost same frequency 2 (1.4%) for Toxoplasmosis and cryptococcal pneumonia and Pneumocystis Pneumonia (PCP) was 1 (0.7%)

Out of 133 patients calculated with Framingham score, 124 people were presented with opportunistic infections, among these the most common found was Tuberculosis (TB) 102 (76.7%), 11 (8.3%) candidiasis, 6 (4.5%) for Tb Meningitis, almost same frequency 2 (1.5%) for Toxoplasmosis and cryptococcal pneumonia and Pneumocystis Pneumonia (PCP) was 1 (0.7%)

Out of 90 patients calculated with SMART score 86 people were presented with opportunistic infections, among these the most commonly found was Tuberculosis (TB) 74 (82.2%), 8 (8.9%) candidiasis, 2 (2.2%) for Toxoplasmosis, cryptococcal pneumonia and Pneumocystis Pneumonia (PCP) was 1 (1.1%)

Table-4: Implication of HAART Associated With Cardiovascular Risk Scores.

HAART COMBINATION	ACC/AHA	FRAMINGHAM	SMART
	SCORE	SCORE	SCORE
	N=141(%)	N=133(%)	N=90(%)
Tenofovir	20(14.2)	19(14.3)	15(16.7)
(TDF)		· · ·	
Tenofovir+Lamuvidine+Effavirenz	47(24.1)	45(24.0)	31(23.3)
(T.TDF+3TC+EFV)			
Lamuvidine+Zudovidine+Neviripine	6(4.3)	6(4.5)	4(4.4)
(3TC+ZDV+NVP)			
Lamivudine	8(5.7)	7(5.3)	2(2.2)
(3TC)			
Atazanavir+Ritonavir+Tenofovir+Emtricitabine (ATV+RTV+TDF+FTC)	6(4.3)	6(4.5)	3(3.3)
Lamuvidine+Zudovidine+Effavirenz	7(5.0)	7(5.3)	6(6.7)
(3TC+ZDV+EFV)	× ,	~ /	~ /
Tenofovir+ Emtricitabine	2(1.4)	2(1.5)	0(0.0)
(TDF+FTC)			, ,
Entacavir (ETV)	1(0.7)	1(0.7)	0(0.0)
Atazanavir+Ritonavir (ATV+RTV)	1(0.7)	1(0.7)	0(0.0)
Tenofovir (TDF)	2(1.4)	1(0.7)	1(1.1)
Effavirenz+Emtricitabine+Tenofovir	24(17.0)	22(16.5)	13(14.4)
(EFV+FTC+TDF)			
Emtricitabine+Tenofovir+Effavirenz (FTC+TDF+EFV)	1(0.7)	1(0.7)	1(1.1)
Emtricitabine+Tenofovir+Effavirenz	8(5.7)	7(5.3)	6(6.7)
(FTC+TDF+EFV)	0(017)	(0.0)	0(017)
Emtricitabine+Tenofovir (FTC+TDF)	1(0.7)	1(0.7)	1(1.1)
Zudovidine+Lamuvidine (ZDV+3TC)	1(0.7)	1(0.7)	1(1.1)
Lamuvidine+Tenofovir+Effavirenz	2(1.4)	2(1.5)	2(2.2)
	2(1.7)	2(1.3)	2(2.2)
(3TC+TDF+EFV)			
Effavirenz+Lamuvidine (EFV+3TC)	1(0.7)	1(0.7)	1(1.1)

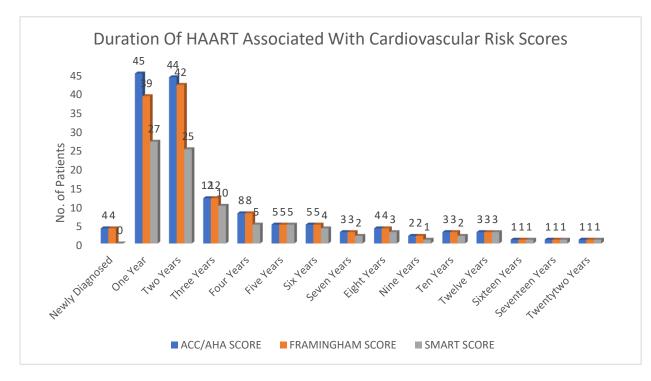
ABACAVIR+LAMUVIDINE (ABC+3TC)	1(0.7)	1(0.7)	1(1.1)
HAART From ART Center (Combination	2(1.4)	2(1.5)	2(2.2)
Unknown)			

Highest prescribed combination was found to be Tenofovir + Lamivudine + Efavirenz (T.TDF+3TC+EFV) 34(24.1%), followed by Effavirenz + Emtricitabine + Tenofovir (EFV+FTC+TDF) 24 (17%), followed by Tenofovir (TDF) 20 (14.2%), followed by Lamivudine (3TC) and Emtricitabine+Tenofovir+Effavirenz (FTC+TDF+EFV) with 8 (5.7%).

Table-5: Duration Of HAART	Associated With	Cardiovascular Risk Scores :
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DURATION	ACC/AHA SCORE	FRAMINGHAM SCORE	SMART SCORE
	N=141(%)	N=133(%)	N=90(%)
Newly Diagnosed	4(2.8)	4(3.0)	
One Year	45(31.9)	39(29.3)	27(30)
Two Years	44(31.2)	42(31.6)	25(27.8)
Three Years	12(8.5)	12(9.0)	10(11.1)
Four Years	8(5.7)	8(6.0)	5(5.6)
Five Years	5(3.5)	5(3.8)	5(5.6)
Six Years	5(3.5)	5(3.8)	4(4.4)
Seven Years	3(2.1)	3(2.3)	2(2.2)
Eight Years	4(2.8)	4(3.0)	3(3.3)
Nine Years	2(1.4)	2(1.5)	1(1.1)
Ten Years	3(2.1)	3(2.3)	2(2.2)
Twelve Years	3(2.1)	3(2.3)	3(3.3)

Sixteen Years	1(0.7)	1(0.7)	1(1.1)
Seventeen Years	1(0.7)	1(0.7)	1(1.1)
Twentytwo Years	1(0.7)	1(0.7)	1(1.1)

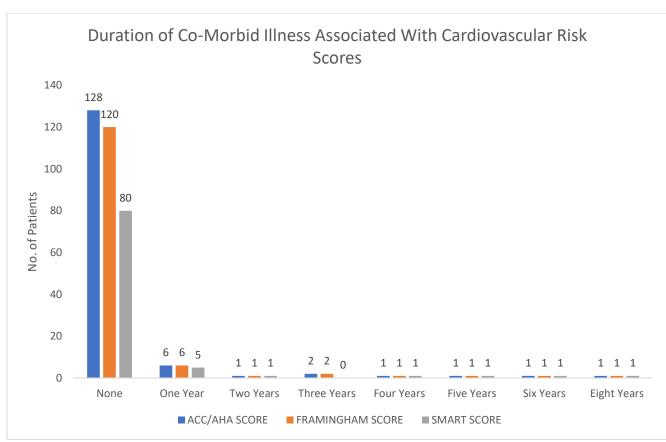


Out of 141 patients, according to ACC/AHA Score highest duration of HAART regimen was observed in one year 45 (31.9%), followed by two years 44 (31.2%), followed by three years 12 (8.5%), followed by four years 8 (5.7%), followed by five and six years with 5 (3.5%), followed by eight years and newly diagnosed with 4 (2.8%), followed by seven years, ten years and twelve years with 3 (2.1%), followed by nine years with 2 (1.4%), followed by sixteen years, seventeen years and twenty two years with 1 (0.7%).

Out of 133 patients, according to Framingham Score highest duration of HAART regimen was observed in two years 42 (31.6%), followed by one year 39 (29.3%), followed by three years 12 (9%), followed by four years 8 (6%), followed by five and six years with 5 (3.8%), followed by eight years and newly diagnosed with 4 (3%), followed by seven years, ten years and twelve years with 3 (2.3%), followed by nine years with 2 (1.5%), followed by sixteen years, seventeen years and twenty two years with 1 (0.7%).

Out of 90 patients, according to SMART Score highest duration of HAART regimen was observed in one year 27 (30%), followed by two years 25 (27.8%), followed by three years 10 (11.1%), followed by four years and five years with 5 (5.6%), followed by six years with 4 (4.4%), followed by eight years and twelve years with 3 (3.3%), followed by seven years and ten years with 2 (2.2%), followed by sixteen years, nine years and twenty two years with 1 (1.1%).

Duration Of Comorbid Illness	ACC/AHA SCORE N=141(%)	FRAMINGHAM SCORE N=133(%)	SMART SCORE N=90(%)
No comorbid illness	128(90.8)	120(90.2)	80(88.9)
One Year	6(4.3)	6(4.5)	5(5.5)
Two Years	1(0.7)	1(0.7)	1(1.1)
Three Years	2(1.4)	2(1.5)	
Four Years	1(0.7)	1(0.7)	1(1.1)
Five Years	1(0.7)	1(0.7)	1(1.1)
Six Years	1(0.7)	1(0.7)	1(1.1)
Eight Years	1(0.7)	1(0.7)	1(1.1)



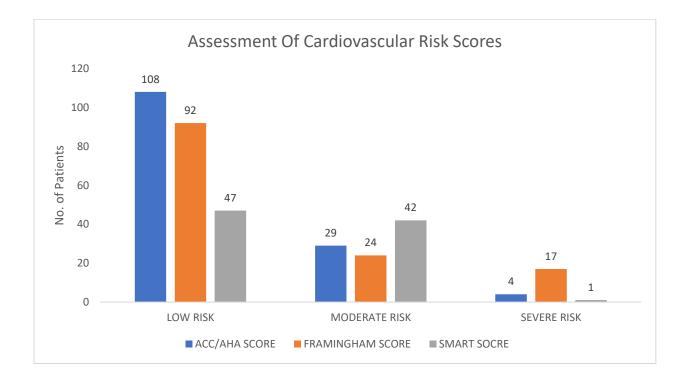
Out of 141 patients enrolled, according to ACC/AHA Score, the highest duration of co-morbid illness was one year 6 (4.3%), followed by three years 2 (1.4%), followed by two, four, five, six and eight years with 1 (0.7%).

Out of 133 patients enrolled, according to Framingham Score, the highest duration of co-morbid illness was one year 6 (4.5%), followed by three years 2 (1.5%), followed by two, four, five, six and eight years with 1 (0.7%).

Out of 90 patients enrolled, according to SMART Score, the highest duration of co-morbid illness was one year 5 (5.5%), followed by two, four, five, six and eight years with 1 (1.1%).

	ACC/AHA	FRAMINGHAM	SMART SOCRE	
	SCORE	SCORE		
	(N=141)	(N=133)	(N=90)	
Low Risk	108(75.9)	92(65.2)	47(33.3)	
Moderate Risk	29(20.6)	24(17.0)	42(29.8)	
Severe Risk	4(2.8)	17(12.1)	1(0.7)	

# Table-7 Assessment Of Cardiovascular Risk Scores



Out of 141 patients enrolled, according to ACC/AHA Score 108 (75.9%) were scored low risk, 29 (20.6%) were scored moderate risk and 4 (2.8%) were scored severe risk.

Out of 133 patients enrolled, according to Framingham Score 92 (65.2%) were scored low risk, 24 (17%) were scored moderate risk and 17 (12.1%) were scored severe risk.

Out of 90 patients enrolled, according to SMART Score 47 (33.3%) were scored low risk, 42 (29.8%) were scored moderate risk and 1 (0.7%) were scored severe risk.

Framingham	AHA Score			Total	Kappa value
Score	Low Risk	Moderate Risk	Severe Risk	(N=90)	value
Low Risk	47	21	0	68	
Moderate Risk	2	3	0	5	0.282
Severe Risk	0	13	4	17	

Table-8 Comparison of AHA Score & Framingham Score

For comparison of all the three scores the N=90 is taken as common.

Out of 90 patients assessed with both Framingham and AHA score, 47 patients were categorized as low risk by both the scores, 21 patients were categorized as low risk by Framingham score whereas they were categorized as moderate risk by AHA score. 2 patients were categorized as moderate risk by Framingham score whereas they were categorized as low risk by AHA score, 3 patients were categorized as moderate by both the scores. 13 patients were categorized as a severe risk by Framingham score whereas they were categorized as a severe risk by Framingham score whereas they were categorized as a severe risk by AHA score & 4 patients were categorized as a severe risk by both the scores.

The Cohen's kappa coefficient value for the degree of agreement between the scores was found to be 0.282 (Fair agreement)

SMART Score	AHA Score			Total	Kappa value
	Low	Moderate	Severe		value
	Risk	Risk	Risk		
Low Risk	40	7	0	47	0.597
Moderate Risk	9	30	3	42	0.577
Severe Risk	0	0	1	1	

 Table-9 Comparison of SMART Score & AHA Score

Out of 90 patients assessed with both SMART and AHA scores, 40 patients were categorized as low risk, 7 patients were categorized as low risk by SMART score whereas they were categorized as a moderate risk by AHA score. 9 patients were categorized as a moderate risk by SMART score whereas they were categorized as low risk by AHA score, 30 patients were categorized as moderate by both the scores. 3 patients were categorized as a moderate risk by SMART score whereas they were categorized as a severe risk by AHA score & 4 patients were categorized as a severe risk by both the scores.

The Cohen's kappa coefficient value for the degree of agreement between the scores was found to be 0.597 (Moderate agreement)

Framingham Score	SMART Score			Total	Kappa value
50010	Low Risk	Moderate Risk	Severe Risk		value
Low Risk	46	22	0	68	
Moderate Risk	1	4	0	5	0.250
Severe Risk	0	16	1	17	

Table-10 Comparison of Framingham Score & SMART Score

Out of 90 patients assessed with both Framingham and SMART score, 46 patients were categorized as low risk by both, 22 patients were categorized as low risk by Framingham score whereas they were categorized as a moderate risk by SMART score. 1 patient was categorized as a moderate risk by Framingham score whereas categorized as low risk by SMART score, 4 patients were categorized as moderate by both the scores. 16 patients were categorized as a severe risk by Framingham score & 1 patient was categorized as a severe risk by both the score & 1 patient was categorized as a severe risk by both the score & 1 patient was categorized as a severe risk by both the score & 1 patient was categorized as a severe risk by both the scores.

The Cohen's kappa coefficient value for the degree of agreement between the scores was found to be 0.250 (Fair agreement)

#### DISCUSSION:

This study included the assessment of CVD risk in PLW-HIV using three different cv risk scores, such as ACC/AHA score, Framingham score and SMART score. The minimum age for calculating the cv risk varied for each score, the minimum age for SMART score was 40 yrs, Framingham was 30 yrs and ACC/AHA was 18 yrs.

Achhra et al found that the risk of all CVD and many cancers increased at low BMI (<18) and high BMI (>30) respectively<sup>(6)</sup>. Our study showed that most of the people have BMI <19.9 and out of which 6 had severe risk of CVD according to Framingham score and 5 people had severe risk in <19.9 range according to ACC/AHA score and 4 people had severe risk in <19.9 range according to SMART score.

Alcohol drinking did not show a significant effect on the variation in the scores, all the three scores depicted almost similar results for the cv risk in people drinking alcohol, although according to Freiberg et al hazardous drinking and alcohol abuse showed a significant increase in cv risk in PLW-HIV when compared to non-drinkers<sup>(7)</sup>.

According to Marcus et al Abacavir combination of HAART showed 2-fold greater risk of cvd than compared to other combinations of HAART. In this study only one patient was prescribed with abacavir based regimen<sup>(8)</sup>.

Cohen's Kappa coefficient is used to find out the degree of agreement between two variables. When the results of the Framingham score was compared with that of the AHA score the kappa coefficient value obtained was 0.282 which shows a fair agreement  $(0.21 - 0.40)^{(9)}$  between these two scores. In a similar way, the results of SMART score was compared with that of AHA score, the kappa coefficient value was 0.597 which shows a moderate agreement (0.41 – 0.60) between the scores. And when the results of the Framingham score were compared with SMART score the kappa coefficient value was 0.250 which shows a fair agreement (0.21 – 0.40) between the scores.



# LIMITATIONS

### LIMITATIONS

# 6. LIMITATIONS:

- The minimum age for calculating the cardiovascular risk scores was different for each score.
- It is a retrospective study comparing three different CV risk scores. Certainly, the best way to compare those scores should be a prospective study observing how these scores work as an HIV cohort grows older.



# CONCLUSION

### CONCLUSION

# 7. CONCLUSION:

This study was conducted to compare the various standard CV risk scores like ACC/AHA score, Framingham score and SMART score in PLW-HIV. All the demographic details of the patients, co-morbid conditions, duration of comorbid conditions, HAART combination prescribed for each patient were documented and compared with respect to each score.

The three cardiovascular risk scores when compared with each other for their degree of agreement showed fair agreement between Framingham and AHA score and Framingham and SMART score and the comparison between AHA and SMART score showed moderate agreement.

ACC/AHA score is the most commonly used score for cv risk scoring India, and when it was compared with Framingham and SMART score showed fair to moderate agreement these scores can also be used in addition to AHA score for calculating cv risk scores in India.



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## **KASTURBA HOSPITAL**

MANIPAL. (An associate Hospital of MAHE, Manipal)

# Kasturba Medical College and Kasturba Hospital Institutional Ethics Committee

(Registration No. ECR/146/Inst/KA/2013/RR-16)

#### Communication of the decision of the Institutional Ethics Committee

ednesday 19th September 2018		IEC: 613/2018
Project title		Comparison of various Cardiovascular risk scores to assess cardiovascular risk in people living with HIV on HAART in Kasturba Hospital Manipal.
Principal Investigator	:	Miss. Kruthiventi Bhavana
Guide/ Co Guide/ Co Investigators	:	Dr. R Rajesh, Dr. Muralidhar Varma
Name & Address of Institution		Dept. of Pharmacy Practice, MCOPS, MAHE, Manipal, Dept. of Medicine, Kasturba Medical College, MAHE, Manipal.
Status of review		New
Date of review		18.09.2018
Decision of the IEC		Approved for the study period from 18.09.2018 to 17.03.2019.

 The PI and all members of the project shall ensure compliance to current regulatory provisions (as per Schedule Y of Drugs and Cosmetics Act and ICH-GCP), Ethical Guidelines for Biomedical Research on Human Participants by ICMR, and the SOP of IEC including timely submission of Interim Annual Report and Final Closure Report

 Participant Information Sheet and a copy of signed Informed Consent shall be given to every research participant

Inform IEC in case of any proposed amendments (change in protocol / procedure, site / Investigator etc)

Inform IEC immediately in case of any Adverse Events and Serious Adverse Events.

Members of IEC have the right to monitor any project with prior intimation.

Dr. Stanley Mathew MEMBER SECRETARY - IEC



IEC Secretariat, Room No. 22, Ground Floor, Faculty Room Complex, Kasturba Medical College Premises, Kasturba Medical College, Manipal - 576104, Karnataka, India. Phone : +91 - 0820 - 2933522, Fax : +91 - 0820 - 2571927. Email : iec.kmc@manipal.edu

NABH





MR-798

(Yoga and Ayurveda services are excluded from the scope of NABH accreditation)

# INDIVIDUAL CASE REPORT FORM

1.Hospital No. : 2. IP No. :			
2.Age :			
3. Sex : Male  Female  Others			
4.Height : 5.Weight : 6.BMI :			
7.B.P : 8.Total cholesterol :			
9.HDL cholesterol :			
10.B.P Medication : Yes I No I			
11.If yes with dose,			
12. Use of Alcohol: Never Social Habitual Reformed			
13. Smoking : Past smoker  Never  Kever  Current Smoker			
14.Diet: Vegetarian  Mixed Diet			
15.Duration of HAART :			
16.Marital Status: Married Unmarried Divorced Widower Separated			
17.Employment: Employed  Unemployed			
18. <b>CD4 Count :</b> a) Initial : b) Final : c) Follow-up			
19.Medical History :			
Diabetes  Coronary Artery Disease			
Cerebrovascular Disease			
Peripheral Artery Disease  Other Cardiovascular Diseases			

20. Time since first diagnosis of Cardiovascular Disease :

21.**Opportunistic Infections :** Present 
Absent

TB Candidiasis CMV TB Meningitis PCP HZ PGL Scabies

Toxoplasmosis 
Cryp. Pneumonia Cryp. Neoformans Cryp. Sporidio

#### 22.HAART Combination :

T. TENVIR	TDF
T. TRIODAY	TDF+3TC+EFV
T. DUOVIR-N	3TC+ZDV+NVP
T. LAMIVIR	3TC
T. QVIR KIT	ATV+RTV+TDF+FTC
T. DUOVIR-EKIT	3TC+ZDV+EFV
T. TENVIR-EM	TDF+FTC
T. LAMIVIR E	D4T+3TC
T. ENTALIV	ETV
T. SYNTHIVAN	ATV+RTV
T. REVIRO	TDF
T. TENOLAM E	TDF+3TC+EFV
T. VIRADAY	EFV+FTC+TDF

#### 23. Framingham Risk Score :

Low risk 🛛	Moderate risk 🛛	Severe risk

#### 24.ACC/AHA Risk Score :

Low risk	Moderate risk	Severe risk

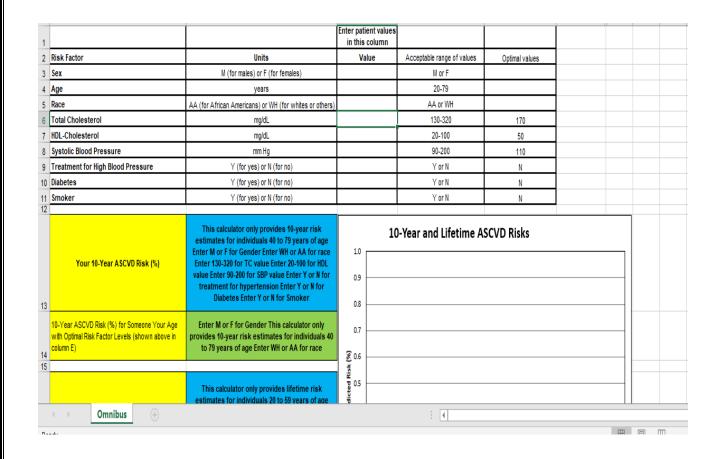
#### 25.SMART Score :

Low risk 
Moderate risk 
Severe risk

### 26.Outcomes based on all the scores :

Low risk 
High risk

# ACC/AHA SCORE:



# FRAMINGHAM RISK SCORE:

Age		years
Sex	Female Male	
Smoker	No Yes	
Total cholesterol	Norm: 150 - 200	mg/dL 与
HDL cholesterol	Norm: 40 - 80 mg/dL	
Systolic BP	Norm: 100 - 120 mm Hg	
Blood pressure being treated with medicines	No	Yes

# **Result:**

Please fill out required fields.

#### Smart risk calculator

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### Enter a whole number between 40 and 80 years

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year(s)

mmol/L

mmol/L

mmHg

#### Gender

Female

#### Current smoking

No

#### Systolic Blood pressure

Enter a whole number between 70 and 2	200mmHg
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#### Medical history

#### **Diabete Melitus**

No

I

#### **Coronary Artery Disease**

No

#### Cerebrovascular Disease

No

#### Abdominal Aortic Aneurysm

No

#### Peripheral Artery Disease

No

1

#### Time since first diagnosis of Cardiovascular Disease

#### Laboratory Results

#### HDL-cholesterol Use median value

Enter a number 0,60 and 2,50 mmol/L

#### Total cholesterol

Enter a number 2,5 and 8 mmol/L