

# **Original Research Article**

## **CARDIOVASCULAR RISK ASSESSMENT AMONG PATIENTS WITH HYPERTENSION PRESENTING AT A FAMILY MEDICINE CLINIC IN SOUTHWEST NIGERIA.**

### **ABSTRACT**

**Aims:** To determine the 10-year cardiovascular risk (CV) and its association with socio-demographic characteristics of hypertensive patients.

**Study design:** This was a cross-sectional study

**Place and Duration of Study:** Family Medicine Clinic of the University College Hospital, Ibadan, Nigeria, between June 2013 and September 2013.

**Methodology:** We included 345 hypertensive patients (84 men, 261 women) aged 30 years and above with no clinical history suggestive of cardiovascular disease. Data collection was with an interviewer-administered semi-structured questionnaire, physical examination and blood investigation. CV risk was determined by using General Framingham cardiovascular risk profile for use in primary care.

**Results:** The mean $\pm$  SD age of the 345 respondents was 57.4 $\pm$ 9.7 years and 75.7% were female. High proportion of the respondents (42.3%) were in the high CV risk category of 10-year risk for cardiovascular disease while 27.0% and 30.7% had intermediate and low CV risk respectively. CV risk was significantly associated with age ( $p < .001$ ), sex ( $p < .001$ ), family type ( $p = .047$ ), level of education ( $p = .02$ ), employment status ( $p < .001$ ) and occupational class ( $p = .007$ ). Logistic regression showed advanced age (OR=0.014, 95% CI =0.002-0.094) and male gender (OR=26.765, 95% CI = 8.802-81.383) as the predictors of high CV risk.

**Conclusion:** The findings show that CV risk assessment should be part of patients' evaluation by physicians and necessary intervention should be instituted on time in order to reduce the burden of cardiovascular disease in Nigeria.

**Keywords:** Hypertension, cardiovascular disease, cardiovascular risk assessment, cardiovascular risk factors.

### **1. INTRODUCTION**

Cardiovascular disease (CVD) is a global health problem and the leading cause of death and disability.

[1,2] The burden of CVD is enormous, having both direct and indirect costs, which are immense to both the individual and the family in terms of medications, rehabilitation, the time off work, to the government on the health care cost and to the country in terms of productivity loss.[1,3] CVDs account for 50% of non-communicable disease death and are responsible for 31% of global deaths, with over 75% of

cardiovascular deaths taking place in low and middle income countries.[1,2] In the Sub-Saharan Africa CVDs account for 11.3% of total deaths and 38.3% of non-communicable disease death.[4]

CVD is a chronic disorder developing insidiously throughout life and progressing to an advanced stage by the time symptoms occur. [5] CVDs are usually seen in middle-aged or elderly individuals. However, atherosclerosis which is the main pathological process leading to CVD begins early in life and progresses gradually. The rate of progression of atherosclerosis is influenced by continuous exposure to the CV risk factors which could be modifiable and non-modifiable. [1,2,4,5] CVD risk factors are multifactorial and they interact over time to produce CVD. [1,2]

Hypertension is an important risk factor for CVD worldwide and it was found to be the most important modifiable risk factor of stroke in Nigeria.[1,2,6] The relationship between blood pressure and the risk of CV events is continuous, consistent and independent of other risk factors.[1,7] In 2010, Gu et al. found that compared to treated controlled hypertensives, treated uncontrolled hypertensives had a 1.74-fold risk of cardiovascular mortality while untreated hypertensives had a 1.37-fold risk of cardiovascular mortality.[8] In a study conducted among an urban Nigerian population with hypertension, more than 46.8% of the participants had above average risk score for CVD. [9]

Furthermore, in patients with hypertension, clustering of various cardiovascular risk factors is high [10,11] thereby increasing the total cardiovascular disease risk. [12] Therefore, management of hypertension requires integrated approaches which include risk assessment for CVD development.

Cardiovascular risk assessment is an objective way of calculating the overall risk of CVD in an individual within a specified period through the use of several prediction models, some of which are developed from Framingham study, application of charts, scores, calculators or equations. The assessment is based on the addition of major CV risk factors. This total CVD risk is the probability of an individual's experiencing a CVD event over a given period of time.

Previous studies have reported the prevalence of various CVD risk factors, [13,14] but information on prevalence of cardiovascular risk factors alone is not sufficient to predict the risk of future cardiovascular event. CV assessment predicts the evolution of target organ damage before its onset and provides an opportunity to initiate preventive strategies promptly, take decision about lifestyle and pharmacologic interventions to reduce such risk.

This study aimed at determining the risk of developing cardiovascular disease (CVD) and the socio-demographic characteristics associated with CV risk among patients with hypertension presenting at Family Medicine Clinic.

## **2. METHODOLOGY**

### **2.1 Study Setting**

The study was carried out at the Family Medicine Clinic of the University College Hospital (UCH), Ibadan, Oyo State. Family Medicine Clinic serves as the point of entry for most patients presenting at UCH with both undifferentiated and differentiated conditions. An average of 300 new and old patients with hypertension are seen monthly at the Family Medicine Clinic.

### **2.2 Study Population**

The study population consisted of adults aged  $\geq 30$  years presenting at Family Medicine Clinic of the UCH from 16<sup>th</sup> of June 2013 to 15<sup>th</sup> of September, 2013 with hypertension and receiving treatment for at least three months with no clinical history suggestive of cardiovascular disease.

### **2.3 Study Design and Sample Size**

It was a hospital based cross-sectional survey. The formula for single proportion was used to calculate the sample size using the 34% prevalence of hypertension among patients attending the Family Practice Clinic at Wesley Guild Hospital, Ilesa Nigeria. [15]

### **2.4 Sampling Method**

A simple random sampling technique was used by means of a computer generated table of random numbers to select a sample of 345 patients with hypertension who were  $\geq 30$  years and had been attending and receiving treatment in Family Medicine Clinic for at least 3 months during the study period.

### **2.5 Data Collection**

A pre-test was done at the General Outpatient clinic of the Jericho Specialist hospital (a Family Medicine Centre) using a randomly selected sample of 20 respondents, who fulfilled the inclusion criteria, in order to validate the research instrument.

Fasting venous blood samples for blood sugar, for the analysis of total cholesterol and high density lipoprotein (HDL) concentration was taken after informed consent from eligible participants who presented fasting the same day. Participants who did not present fasting were requested to come fasting for at least 8 hours the following day. After each participant was through with the blood sample collection, corrected version of the questionnaire was administered by the research assistant while the researcher took the blood pressure measurement and physical examinations.

## **2.6 Instruments for Data Collection**

Socio-demographic characteristics, antihypertensive medication use, history of diabetes and current smoking status were obtained. Occupation was grouped into social classes as described by Boroffka and Olatawura. [16] Class I=Professional with university degree, Class II= Professional without university degree, Class III= Small scale entrepreneur, Class IV= Small scale farmer, Class V=Labourer, Petty trader, Class VI=Unemployed, Pensioner, Full time housewife, Clergy, Muslim Cleric. Average monthly income was classified as living below and above poverty line which was stated as earning above or below \$1.25 per day which was equivalent to above ₦6,000 per month. [17]

The participant's blood pressure was determined with the use of a Dekamet MK3 sphygmomanometer made by Accoson<sup>R</sup> in England. The blood pressure measurement was done twice at one-minute interval (after 30 minutes' rest) with the respondents in a calm seated position with arm supported at heart level. Appropriate cuff size was used for each patient, encircling at least 80% of the arm. The cuff was inflated rapidly to about 30 mmHg above the level at which the radial pulse was no longer palpable, followed by slow deflation. The first korotkoff sound was taken as the systolic value, while the phase five of the sound was the diastolic value. The observed value was recorded to the nearest 2 mmHg. [7] An average of the two readings taken at one-minute interval was used.

Blood sample was obtained from the participants in the morning (7. 30a.m-9am) after an overnight fast (8-12 hour fast). The glucometer used was calibrated using standard test strips supplied by the manufacturer

and compared with the UCH chemical laboratory reading (randomly selected samples) to ensure that the readings were accurate. Blood glucose of each participant was determined by putting a drop of venous whole blood on the strip of a glucometer (Accu-Chek Advantage, Roche Diagnostics, Mannheim, Germany) while the remaining of the blood sample was put in an Ethylenediaminetetracetic acid (EDTA) bottle.

In a Nigerian Family Practice population, glucometer was found to be a reliable tool for screening patients for diabetes mellitus (DM), with a positive predictive index of 96%. [18] DM is taken as fasting blood glucose greater or equal to 6.1mmol/l(110mg/dl) or fasting plasma glucose greater or equal to (7mmol/l) 126 mg/dl or previously diagnosed as having DM and had been on medication for DM. [19] Patients whose fasting blood glucose level was above 6mmol/L had confirmatory fasting plasma glucose determination by the standard spectrophotometric method in UCH chemical laboratory.

The blood sample in an EDTA bottle was centrifuged at 3500 revolutions per minute (rpm) for 5minutes (using Centaur 2 MSE centrifuge). The plasma obtained after centrifugation was collected into a plain tube and stored at 4°C if analysis was not done the same day. The analyses were done by a qualified Laboratory Scientist. HDL-cholesterol and total cholesterol were measured using spectrophotometric methods. Laboratory kit reagents (Lot number 2121CH) from Randox Laboratories Limited, United Kingdom were used for all biochemical analysis and their absorbance were read using a Spectro scan 60 DV spectrophotometer (Biotech engineering management co. ltd. UK) at 500nm wavelength.

Framingham General cardiovascular risk score for use in primary care was used to estimate the 10-year risk of developing CVD. Framingham General cardiovascular risk score is a sex-specific multivariable risk functions that estimates the 10-year CVD risk of an individual according to age, total cholesterol, HDL cholesterol, systolic blood pressure, antihypertensive medication use, current smoking, and diabetes status. It was developed by D'Agostino et al. from Framingham heart study in 2008. [20] A high, intermediate and low CVD risk is a 10-year score >20%, 10%-20% and <10% respectively. The 10-year CVD risk level for each participant was obtained from the total risk score that was calculated from the number of points for each risk.

## **2.7 Data Analysis**

Data analysis was done with the Statistical Package for Social Sciences (SPSS) version 17 after sorting and coding the questionnaire. Frequency tables were generated for relevant variables. Descriptive statistics such as mean and standard deviations were used to summarize quantitative variables while categorical variables were summarized with proportions and percentages. The Chi- square test was used to investigate associations between socio-demographic factors and CV risk. Multivariate analysis (logistic regression) was used to explore significant variables with CV risk. All analysis was done at 5% level of significance.

### 3. RESULTS

The Socio-demographic characteristics of the respondents are shown in Table 3.1. The mean $\pm$  SD age of the respondents was 57.4 $\pm$ 9.7 years with a range of 35-82 years. The highest number of respondents 141 (40.9%) were in the age group 50-59 years and the male to female ratio was 1:3.1. Majority of the respondents were currently married (71.9%), in monogamous marriage (65.5%), had formal education (75.4%) and were currently employed (81.7%). One hundred and forty-one (40.9%) respondents were in occupational class V while 73 (21.2%) were in occupational class I and majority 259 (75.1%) were living above the poverty level.

**Table 3.1: The Sociodemographic characteristics of the respondents**

Variables	(N=345)	
	Frequency (n)	Percentage (%)
<b>Age (years)</b>		
<50	65	18.8
50-59	141	40.9
60-69	95	27.5
70 and above	44	12.8
<b>Sex</b>		

Male	84	24.3
Female	261	75.7
<b>Marital status</b>		
Currently married	248	71.9
Not currently married	97	28.1
<b>Family type</b>		
Monogamous	226	65.5
Polygamous	119	34.5
<b>Level of education</b>		
Had no formal	85	24.6
Had formal	260	75.4
<b>Employment status</b>		
Currently employed	282	81.7
Not employed	63	18.3
<b>Occupational class</b>		
Class I	73	12.2
Class II	21	6.1
Class III	34	9.8
Class IV	12	3.4
Class V	141	40.9
Class VI	64	18.6
<b>Monthly income</b>		
Below poverty line	86	24.9
Above poverty line	259	75.1

Table 3.2 shows some medical parameters of the respondents. All the respondents were on medication for hypertension. The median duration of medication use was 6.0years. Fifty-three (15.4%) respondents were on one antihypertensive while 292 (84.6%) took two or more anti-hypertensives for blood pressure

control. Nineteen (5.5%) of the respondents reported having ever smoked cigarette however, none of them was a current smoker while 122 (35.4) were diagnosed to have diabetes mellitus (DM).

Majority (79.7%) of the respondents had abnormal HDL-C with higher proportion in female (91.2%) while 14.8% respondents had hypercholesterolaemia.

**Table 3.2: Medical parameters of the respondents**

Variable	Male n=84 (%)	Female n=261 (%)	Total N=345 (%)
Number of antihypertensives			
1	16 (19.0)	37 (14.2)	53 (15.4)
2	38 (45.2)	127 (48.7)	165 (47.8)
3	21 (25.0)	80 (30.7)	101 (29.3)
>4	9(10.8)	17 (6.5)	26 (7.5)
Ever smoked			
Yes	18 (21.4)	1 (0.4)	19 (5.5)
No	66 (78.6)	260 (99.6)	326 (94.5)
Having diabetes mellitus			
No	56 (66.7)	167 (64.0)	223 (64.6)
Yes	28 (33.3)	94 (36.0)	122 (35.4)
Total cholesterol (mg/dl)			
Abnormal	15 (17.9)	36 (13.8)	51 (14.8)
Normal	69 (82.1)	225 (86.2)	294 (85.2)
HDL-C level (mg/dl)			
Abnormal	37 (44.0)	237(91.2)	275 (79.7)
Normal	47 (56.0)	23 (8.8)	70 (20.3)



The Cardiovascular risk (CV) of the respondents is shown in table 3.3. One hundred and forty-six (42.3%) of the respondents had high CV risk, while 93 (27.0%) had intermediate CV risk and 106 (30.7%) had low CV risk. Majority 55 (65.5%) of the male respondents had high CV while 91 (34.9%) of the female respondents had high CV. The mean score  $\pm$ SD for male and female respondents were 21.5 $\pm$  9.2 and 15.7 $\pm$ 10.1 respectively.

**Table 3.3: Cardiovascular risk of the Respondents**

<b>Variables</b>	<b>Male=84</b>	<b>Female=261</b>	<b>Total= 345</b>
	<b>n (%)</b>	<b>n (%)</b>	<b>N (%)</b>
<b>Low risk</b>	15 (17.9)	92 (34.9)	106 (30.7)
<b>Intermediate risk</b>	14 (16.6)	78 (30.2)	93 (27.0)
<b>High risk</b>	55 (65.5)	91 (34.9)	146 (42.3)

Association between CV risk and socio-demographic characteristics of respondents is shown in table 3.4. There was a significant association between age, sex, family type, level of education, employment status, occupational class and CV risk. Higher proportion of respondents (64.2%) between 60-69 years had a high CV risk while higher proportion of those less than 50 years of age (58.5%) had low CV risk and this was statistically significant at  $\chi^2= 57.488$ ,  $p<.001$ . Higher proportion of males 55 (65.5%) had a high CV risk compared to females 91 (34.9%). This was also statistically significant at  $\chi^2= 1.638$ ,  $p<.001$ . Significantly, those with no formal education had a higher proportion of respondents with high CV risk (54.1%). Also, a higher proportion of respondents belonging to occupational class VI (65.6%) had high CV risk compared with those in occupational class I (32.9%). This was statistically significant at  $\chi^2 = 24.269$ ,  $p=.01$ .

**Table 3. 4: ASSOCIATION BETWEEN CARDIOVASCULAR RISK AND SOCIO DEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS**

Variable	CV risk			Total	$\chi^2$	p value
	High (%)	Intermediate (%)	Low (%)			
Age (years)						
<50	10 (15.2)	17 (26.3)	38 (58.5)	65 (100.0)	57.4	<0.0001*
50-59	49 (34.8)	44 (31.2)	48 (34.0)	141(100.0)	88	
60-69	61 (64.2)	21 (22.1)	13 (13.7)	95 (100.0)		
70 and above	26 (59.1)	11 (25.0)	7 (15.9)	44 (100.0)		
Sex						
Male	55 (65.5)	14 (16.8)	15 (17.9)	84 (100.0)	1.63	<0.0001*
Female	91 (34.9)	79 (30.2)	91 (34.9)	261 (100.0)	8	
Marital status						
Currently married	100 (40.3)	66 (26.6)	82 (33.1)	248 (100.0)	5.85	0.441
Not currently married	46(47.4)	27 (27.8)	24 (24.7)	97 (100.0)	4	
Family type						
Monogamous	87 (38.5)	60 (26.5)	78 (35.0)	226 (100.0)	6.12	0.047*
Polygamous	59 (49.6)	33 (27.7)	27 (22.7)	119 (100.0)	1	
Level of education						
Had no formal	46 (54.1)	26 (30.6)	13 (15.3)	85 (100.0)	13.0	0.002*
Had formal	100 (38.5)	67 (25.8)	93 (35.7)	260 (100.0)	03	
Employment status						
Currently employed	104 (36.9)	85 (30.1)	93 (33.0)	282 (100.0)	19.1	<0.0001*
Not employed	42 (66.7)	8 (12.7)	13 (20.6)	63 (100.0)	63	
Occupational class						
Class I	24 (32.9)	19 (26.0)	30 (41.1)	73 (100.0)	24.2	0.007*
Class II	10 (47.6)	4 (19.0)	7 (33.4)	21 (100.0)	69	
Class III	13 (38.2)	13 (38.2)	8 (23.5)	34 (100.0)		
Class IV	4 (33.3)	3 (25.0)	5 (41.7)	12 (100.0)		
Class V	53 (37.6)	45 (31.9)	43 (30.5)	141 (100.0)		

Class VI	42 (65.6)	9 (14.1)	13 (20.3)	64 (100.0)
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#### Monthly income

Below poverty line	40 (46.5)	25 (29.1)	21 (24.4)	86 (100.0)	2.14	0.342
Above poverty line	106 (40.9)	68 (26.3)	85 (32.8)	259 (100.0)	8	

\*significant at P<.05

Logistic regression of significant socio-demographic variables on high CVD risk is presented in the table 3.5 below. Respondents less than 50 years of age were about 71 times less likely to have a high CVD risk compared to those 70 years and above (OR=0.014; 95%CI=0.002-0.094). Those between 50-59 years were about 11 times less likely to have a high CVD risk compared to those 70 years and above (OR=0.094; 95%CI=0.020-0.445). Male respondents were 26 times more likely to have a high CVD risk compared to females (OR=26.765; 95%CI=8.802-81.383). All these were statistically significant.

**Table 3.5: Logistic regression of significant socio-demographic variables on high cardiovascular risk**

Variable	Regression coefficient( $\beta$ )	Wald	p value	Odds ratio	95% Confidence Interval
<b>Age (years)</b>					
<50	-4277	19.301	<0.0001*	0.014	0.002-0.094
50-59	-2.368	8.860	0.003	0.094	0.020-0.445
60-69	-0.293	0.193	0.660	0.746	0.202-2.752
70 and above				1	
<b>Sex</b>					
Male	3.287	33.563	<0.0001*	26.765	8.802-81.383
Female				1	
<b>Family type</b>					
Polygamous	-0.693	2.275	0.132	0.500	0.203-1.231
Monogamous				1	
<b>Level of education</b>					
Formal	0.282	0.298	0.633	1.325	0.418-4.207
No formal				1	
<b>Employment status</b>					
Currently employed	-2.006	1.665	0.197	0.135	0.006-2.831
Not employed				1	

<b>Occupational class</b>					
Class I	1.161	0.527	0.468	3.193	0.139-73.332
Class II	1.466	0.726	0.394	4.332	0.149-126.347
Class III	1.574	0.906	0.341	4.827	0.189-123.558
Class IV	1.253	0.442	0.506	3.500	0.087-140.507
Class V	1.089	0.497	0.481	2.971	0.144-61.324
Class VI				1	

\*Significant at  $P < .05$

#### 4. DISCUSSION

Majority of the respondents in this study were young and middle aged adults. This finding is similar to that of Chiazor and Opara, in which 61.0% of patients with hypertension were below 60 years. [21] However, blood pressure had been shown to increase steadily with age irrespective of gender. [7] Majority of the respondents were found to live above the poverty line, this finding might be due to the fact that most of the study population were in the labour force in Nigeria, which is within the age range of 15-64 years. [22] Majority of the respondents were using more than one antihypertensive. This is consistent with the treatment guideline recommended by JNC-7 for hypertension treatment, that most patients with hypertension will require two or more anti hypertensives to achieve the target BP. [7] This indicates that majority of the respondents were not having mild hypertension. One third of the respondents had coexisting DM but none was smoking currently. The present study is hospital based and contacts of the respondents with the health personnels could have increased their cardiovascular knowledge and the resultant change in lifestyle such that none was a current smoker.

The high risk probability of developing CVD over 10 years in this study is high. This finding may be due to the fact that hypertension is a CVD and an important **etiological** risk factor for the development of other CVDs. The substantial percentage in the intermediate and low risk category will require life style modification and pharmacologic intervention initiation. Also, the difference in 10-year risk score category between male and female is similar to the findings by Ezeanyika et al. in assessment of cardiovascular disease risk of an urban Nigerian hypertensive population. [9]

The finding that CV risk increases with advancing age was confirmed by this study. [1,4] In this study population, almost two third of the respondents between 60-69 years had a high CV risk while more than half of the respondents with low CV were less than 50 years of age and this was significant ( $p<0.001$ ). The explanation for this is that the prevalence of CV risk factors in an individual increase with age. Ejim et al. found that in a rural community in South East Nigeria, the prevalence of CVD risk factors was highest in patients aged 65 to 70 years. [23]

There is a statistical significant difference in 10-year risk score category between male and female. This is similar to previous evidence derived from the Framingham Heart study population and is consistent with a previous study in Nigeria by Ezeanyika. [9] The higher risk of CVD in men may be due to genetic, hormonal, poor adherence to medications or lifestyle factors or a combination of mechanisms. [24,25,26] Premenopausal women have hormonal protective effect of estrogen which slowed progression of CVD. [26]

Significantly also, more than half of the respondents with no formal education had high CV risk. This is consistent with a report that low educational level was shown to confer a greater lifetime risk of CVD. [27] This could be explained by the fact that patients' level of education may have positive influence on understanding specific health education programmes and relevant behavioural change which would eventually reduce CV risk. Similarly, those who were not employed, those belonging to occupational class VI, in polygamous union and living below poverty line had high CV risk compared to their counterpart. These factors determine the socioeconomic status of the respondents, poor socioeconomic factors are barriers to medication adherence and good adherence is essential for achieving good blood pressure control and ultimately reducing CV risk. [28,29] The predictors for high CV risk identified in this study were advancing age and male gender. This is consistent with findings from Framingham study and the finding that advancing age is an independent risk factor for CVD. [1,4]

This study had determined the cardiovascular risk of patients with hypertension, however it should be interpreted with caution as it was a clinic-based study, which may not necessarily be a complete reflection of the real picture in the general populace.

## 5.0 CONCLUSION

Given the high risk probability of developing CVD over 10 years in this study, preventive intervention strategy should be part of health care programme in the Family Medicine Clinic of developing countries and Physicians during day to day encounters with patients with hypertension should screen for other CV risk factors.

## ETHICAL CONSIDERATIONS

Ethical clearance for the study was obtained from the Ethical Committee of the University of Ibadan/ University College Hospital Institutional Review Board (UI/UCH IRB) [registration number NHREC/05/01/2008a]. Permission was also granted by the Head, Department of Family Medicine, University College Hospital, Ibadan. Respondents were informed that participation was voluntary. Informed consent was obtained from each participant prior to data collection. Confidentiality was maintained and privacy was ensured. The study was not harmful, the participants who agreed to participate only experienced a minimal discomfort when blood sample (5mls) was being taken for investigation by the researcher. The investigations done were at no cost to the participants.

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## INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT)

COLLEGE OF MEDICINE, UNIVERSITY OF IBADAN, IBADAN, NIGERIA.

Director: Prof. A. Ogunniyi, B.Sc(Hons), MBChB, FMCP, FWACP, FRCP (Edin), FRCP (Lond)

Tel: 08023038583, 08038094173

E-mail: aogunniyi@comui.edu.ng



UI/UCH EC Registration Number: NHREC/05/01/2008a

### NOTICE OF FULL APPROVAL AFTER FULL COMMITTEE REVIEW

Re: Cardiovascular Risk Assessment and Family Support in Patients with Hypertension  
Presenting at Family Medicine Department, University College Hospital, Ibadan

UI/UCH Ethics Committee assigned number: UI/EC/12/0143

Name of Principal Investigator: **Dr. Helen T. Ilori**

Address of Principal Investigator: Department of Family Medicine,  
University College Hospital, Ibadan

Date of receipt of valid application: 25/05/2012

Date of meeting when final determination on ethical approval was made: N/A

This is to inform you that the research described in the submitted protocol, the consent forms, and other participant information materials have been reviewed and given *full approval* by the *UI/UCH Ethics Committee*.

This approval dates from 11/10/2012 to 10/10/2013. If there is delay in starting the research, please inform the UI/UCH Ethics Committee so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the UI/UCH EC assigned number and duration of UI/UCH EC approval of the study.* It is expected that you submit your annual report as well as an annual request for the project renewal to the UI/UCH EC early in order to obtain renewal of your approval to avoid disruption of your research.

*The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the UI/UCH EC. No changes are permitted in the research without prior approval by the UI/UCH EC except in circumstances outlined in the Code. The UI/UCH EC reserves the right to conduct compliance visit to your research site without previous notification.*



Prof. A. Ogunniyi  
Director, IAMRAT  
Chairman, UI/UCH Ethics Committee  
E-mail: [uiuchirc@yahoo.com](mailto:uiuchirc@yahoo.com)

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