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OUTCOMES OF COMMUNITY PHARMACIST' CARDIOVASCULAR RISK INTERVENTION AMONG HIGH RISK RURAL DWELLERS

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ABSTRACT: Community pharmacists are well placed to contribute to reduction of premature deaths from cardiovascular disease by implementing risk assessment and reduction strategies. The objective of this study was to assess outcomes of pharmacist's cardiovascular risk reduction intervention among high risk persons dwelling in a rural community. Cardiovascular risk reduction intervention was carried out among 45 high risk patients using a non-randomized before and after design. Blood pressure, total cholesterol, random blood sugar and BMI were measured. Intervention consisted of leaflet based patient education, referral to physician and provision of prescribed medications at no charge. Data were expressed as mean, standard deviation and 95% confidence interval. Differences between baseline and post intervention values were explored using paired t test. The primary outcome measure was change in cardiovascular risk category between baseline and end of study. The results show that there were significant differences in blood pressures at baseline vs. post-intervention, (184.74 ± 15.78 *vs.* 138.69 ± 13.57; $P < 0.001$), and (102.17 ± 15.14 *vs.* 82.62 ± 9.45, $P < 0.001$) for systolic and diastolic blood pressures respectively. There were no statistically significant differences in other clinical characteristics. Of the 9 males in high risk category at baseline, all were reclassified as low risk at the end of the study. At baseline 10 females in the high risk category were reclassified as low risk while 19 of the 23 in the very high risk category were reclassified as low risk (82.6%). These findings indicate that pharmacist's interventions lowered cardiovascular risk among high risk rural community dwellers.

INTRODUCTION: Cardiovascular disease (CVD) is a major cause of death worldwide. The World Heart Federation projections indicate that by 2030, deaths from heart disease will reach an alarming 28.6 million annually [1-2].

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Cardiovascular diseases claim more lives annually than all forms of cancers combined. Disability Adjusted Life Years (DALYs) lost due to cardiovascular disease ranks next only to HIV / AIDS. Mortality from CVD cuts across age, gender and socioeconomic status.

In fact, deaths from cardiovascular diseases among 15-35 age group in the United States of America is estimated to be 10.2 per 100,000 making it the 5th leading cause of death among this age group [3]. Also, there is increasing prevalence of risk factors for cardiovascular disease in low income countries

and an estimated 80% of deaths from cardiovascular disease are in these countries [4]. Risk factor assessment is a critical first step in primary prevention of cardiovascular disease. There is sufficient evidence to prove that controlling risk factors reduces cardiovascular mortality [5 - 8]. Reducing cardiovascular risk requires prompt and sustained lifestyle interventions as well as drug therapy following evidence based approach. Access and availability are strong points that justify use of pharmacists in delivering preventive health services including cardiovascular risk assessment. Pharmacists have demonstrated effectiveness in the area of cardiovascular risk interventions at the level of the community pharmacy [9 - 13], but involvement in population based interventions is quite low. Population based risk assessment involves proactively targeting healthy persons within the population and inviting them for assessment.

Objective: The general objective of this study was to assess outcomes of the pharmacist's interventions in cardiovascular risk reduction in the community. Specific objectives were to determine difference in blood pressure, blood glucose, and total cholesterol levels between baseline and end of study, and to evaluate pharmacotherapy components of intervention.

Setting: The setting of this study is Ezionum, a rural community in Ukwuani Local Government Area of the oil rich Delta state. Nigeria. The community has a primary health center that caters to their health needs. The general hospital located at Obiaruku, about 3 kilometres from the community serves as a referral centre for more serious cases. The community also serves as a site for Community Based Experience and Services (COBES) program for medical and nursing students of the Delta State University, Abraka. This study is a follow up to a general cardiovascular risk assessment carried out in the community.

MATERIALS AND METHODS:

Design: The study is a non- randomized single site before and after interventional study carried out between August 2015 and April 2016.

Patients / Population Inclusion and Exclusion Criteria: A total of 42 high CV risk category patients identified from a community wide general cardiovascular risk screening exercise using the WHO/ISH risk assessment charts were recruited for the study. All patients who met the inclusion criteria were evaluated. Inclusion criteria were: Adults 40 years to 80 years old and persons at high risk of cardiovascular events *i.e.* 10 year risk score of > 20 – 40%. Patients under active care of a physician, who were pregnant, below 40 years of age, unwilling to participate in the study or who were unlikely to be available for follow up were excluded from the study.

Data Collection Instruments: The main risk assessment tool was the WHO/ISH risk assessment chart for Africa D epidemiological zone [14]. This was a country specific validated tool that makes use of age, gender, systolic blood pressure, smoking status, diabetes status and total non-fasting cholesterol in estimating cardiovascular risk. The point of intersection of systolic blood pressure and total serum cholesterol on the chart is colour coded to determine cardiovascular risk level. Demographic and clinical characteristics as well as risk score and risk category were entered into a data collection form designed for the study. Patients were evaluated after signing an informed consent form.

Intervention: Intervention consisted of leaflet based patient education focusing on risk factors and risk reduction strategies especially healthy lifestyle options. In addition subjects were also given a single page fact sheet relating to their specific risk factor. For subjects that were overweight a height and ideal weight chart was also made available to help them set weight targets. Referral to the physician was a critical component of the intervention. To facilitate the referral process, a cardiovascular risk assessment referral form detailing risk assessment data and reasons for referral was designed. Other measures adopted were: weekly telephone / text message reminders, and regular appointments with patients to review progress and resolve any medication related problems. Prescribed medications were also provided at no charge to indigent subjects for the duration of the study. Intervention period was 6 months.

Outcome Measures: The primary outcome measure was change in cardiovascular risk category

between baseline and end of study. Secondary outcome measures were: Difference in levels of measured risk factors between baseline and end of study *i.e.* blood pressure, blood glucose, heart rate.

Data Analysis: Data were expressed as mean, standard deviation and 95% confidence interval. Differences between baseline and post intervention values were explored using paired t test. Predictors of high risk category were identified by performing multiple linear regression analysis. A p value of 0.05 was regarded as statistically significant.

Ethical Approval: Ethical approval was obtained from the Delta State University Health Research Ethics Committee, Oghara. Approval letter number DELSUTH/HREC/2015/038.

RESULTS:

TABLE 1: DEMOGRAPHIC CHARACTERISTICS OF PATIENTS

Characteristic		No %	n = 42
Sex	Male	9	21.4
	Female	33	78.6
Age (yr.)	40-50	5	11.9
	51-60	15	35.7
	61-70	9	21.4
	>70	13	31.0
Tobacco use	No	39	92.9
	Yes	3	7.1
Alcohol intake	Light	23	60.5
	Heavy	8	21.1
	I don't drink alcohol	11	18.4
Physical activities	0 times a week	4	9.5
	Once a week	3	7.2
	2 times a week	11	26.1
	3 times a week	6	14.3
	Every day	16	38.1
	No response	2	4.8
Chronic disease	Diabetes	4	9.5
	High blood pressure	14	33.3
	None	24	57.2

Demographic and Clinical Characteristics: A total of 45 patients at high risk of cardiovascular disease were recruited for the study. Of these, one patient had stroke before the end of the study and two patients were lost to follow up. Majority of the 42 patients that completed the study (78.6%) were females. The predominant age group was 51 to 60 years 15 (35.7%) followed by those in the above 70 age group 13 (31%). Majority 31 (81.5%) consumed alcohol and more than half 22 (53%) were engaged in moderate physical activity for at least 3 times a week. Only one third 14 (33.3%) correctly identified themselves to be hypertensive while 4 (22.8%) had diabetes. Demographic and clinical characteristics of patients at baseline are presented in **Tables 1** and **2.**

TABLE 2: CLINICAL CHARACTERISTICS OF PATIENTS AT BASELINE

Characteristic	No (%) n = 42
Blood Pressure Systolic	
140 – 159	1 (2.3)
160 – 169	6 (14.3)
170 – 189	18 (42.9)
≥ 190	17 (40.5)
Diastolic	
≤ 90	9 (21.4)
91 – 99	4(9.5)
100 – 109	17 (40.5)
110 – 119	5 (11.9)
≥ 120	7 (16.7)
Heart rate (bpm)	
≤ 90	27(64.3)
91 – 99	11(26.2)
≥ 120	4(9.5)
Total cholesterol (mm /L)	
1 – 4.9	26 (61.9)
5 – 8.0	16 (38.1)
Fasting blood glucose	
‹ 7mmol/L	37(88.1)
≥ 7mmol/L	5 (11.9)
Body Mass Index	
Less than 18.5 (Underweight)	2 (4.8)
18.5 – 25 (Normal)	18 (42.8)
> 25 – 29.9 (Overweight)	17 (40.5)
≥30(Obese)	5 (11.9)
Waist Circumference	
Male	N = 9
≤ 102 cm	5 (55.6)
> 102cm	4 (44.4)
Female	N = 33
≤88cm	15 (45.5)
>88cm	18 (54.5)

The clinical characteristics at end of study and the mean differences in values post intervention are shown in **Tables 3** and **4**. There were significant differences in systolic and diastolic blood pressures before and after intervention (184.74 ± 15.87 *vs*. 138 ± 13.57, P < 0.001 and 102.17 ± 15.14 *vs*. 82.62 ± 9.45 < 0.001) respectively. Though total cholesterol, heart rate, blood sugar levels, and waist circumference did not show significant differences, the upper limits of the 95% confidence interval for these variables showed moderate reductions at post intervention when compared to baseline, **Table 5.**

TABLE 3: CLINICAL CHARACTERISTICS OF PATIENTS AT END OF STUDY

Characteristic	No (%) n = 42
Blood Pressure Systolic	
<120	1 (2.3)
120 – 139	18 (42.9)
140 – 159	17 (40.50)
≥ 160	6 (21.4)
Diastolic	
≤ 80	8 (19.1)
80 – 89	19 (45.2)
90 – 99	14 (33.3)
≥ 100	1 (2.4)
Heart rate (bpm)	
≤ 90	30 (71.4)
91 – 99	11 (26.3)
≥ 120	1 (2.3)
Total cholesterol (mm /L)	
1 – 4.9	34(81.0)
5 – 8.0	8 (19.0)
Fasting blood glucose	
‹ 7mmol/L	28 (66.7)
≥ 7mmol/L	14 (33.3)
Body Mass Index	
Less than 18.5 (Underweight)	1 (2.4)
18.5 – 25 (Normal)	18 (42.8)
> 25 – 29.9 (Overweight)	16 (38.1)
≥30(Obese)	7 (16.7)
Waist Circumference	
Male	N = 9
≤ 102 cm	8 (88.9)
> 102cm	1(1.1)
Female	N = 33
≤88cm	17 (51.5)
>88cm	16 (48.5)

TABLE 4: CLINICAL CHARACTERISTICS AT BASELINE AND POST INTERVENTION

Clinical characteristics	Pre intervention mmHg n = 42 Mean (SD)	Post intervention mmHg n = 42 Mean (SD)	T	P value
Systolic blood pressure	184.74± 15.87	138.69±13.57	15.848	<0.001
Diastolic blood pressure	102.17± 15.14	82.61± 9.45	8.768	<0.001
Total Cholesterol	4.45±0.97	4.40± 0.49	0.424	0.674
Heart rate	85.05± 12.94	83.74 ±9.95	1.431	0.160
Body Mass Index	25.76 ±4.77	25.99± 4.01	-0.617	0.515
Fasting blood sugar	6.00 ±2.26	7.16 ±2.17	-3.461	0.001
Waist Circumference	91.33 ±14.31	91.40±12.34	-102	0.919

TABLE 5: CLINICAL CHARACTERISTICS AT BASELINE AND POST

Clinical characteristic	Mean (95% CI)			
	Male		Female	
	Baseline	Post intervention	Baseline	Post intervention
Systolic blood pressure	178 (162.0-193.5)	140 (127.36-152.63)	187.56 (182-192.83)	139.21 (134.59-143.84)
Diastolic blood pressure	98.87 (77.34-120.41)	83.18 (77.23-89.01)	99.11 (99.1-107.76)	82.96 (79.33-86.60)
Total cholesterol	4.83 (3.67-5.97)	4.6 (4.60-4.70)	4.36 (4.05-4.66)	4.35 (4.17-4.53)
Heart rate	91.5 (78.16-104.83)	88 (88.04-95.95)	84.21 (79.92-88.51)	83.15 (79.53-86.78)
Body Mass Index	27.7 (23.03-32.49)	27.35 (22.88-31.79)	25.08 (23.44-26.73)	25.61 (24.29-26.93)
Fasting blood glucose	8.1 (4.4-11.76)	7.77 (6.35-7.84)	5.54 (5.17-5.90)	7.10 (6.35-7.84)
waist circumference	97.75 (83.50-112)	90.06 (85.11-95.02)	97.5 (85.58-109.41)	89.93 (85.70-94.12)

Intervention Stratified by Gender: All males enrolled in the study had favourable risk category changes while 9.5% of females were at high risk at the end of the study despite intervention, **Table 6**.

TABLE 6: RISK CATEGORY AT THE END OF STUDY

	Male		Female	
Risk category	Baseline n (%)	Post intervention N (%)	Baseline n (%)	Post Intervention n (%)
Very high	0(0)	0(0)	23(54.76)	0(0)
High	9 (21.5)	0(0)	10(23)	4(9.5)
Low	0(0)	9 (21.5)	0(0)	29(69)

Pharmacotherapy Component: All the subjects were on prescribed medications at the end of the study. Majority were on 2 or 3 drug combination therapy for hypertension at the end of study. There were more patients on ACEI followed by potassium sparing low dose diuretic and methyl dopa. Low dose aspirin was the sole anti-platelet agent which was prescribed for more than a quarter of the patients. All medications provided were generic brands and monthly cost of drug therapy ranged from N280 ($ 0.7) to N2360 ($ 5.9), **Table 7** and **8**.

TABLE 7: SUMMARY OF PRESCRIBED MEDICATIONS AT THE END OF STUDY

Drug	No of patients n (%)	No of tablets per dose	No of tablets per day	Cost per tab Naira	Cost of daily dose Naira
Methyl dopa	18(42,86)	1	3	20.00	60.00
Amlodipine 10 mg	16(38.10)	1	1	14.29	14.29
Lisinopril 10 mg	22(52.38)	1	1	14.29	14.29
Nifedipine 20 mg	5(11.90)	1	2	15	30.000
Atenolol 50mg	1(2.40)	1	2	15	30.00
Co Amiloride	19(45.20)	1	1	10	10.00
Valsartan	1(2.40)	1	1		
Hydrochlorothiazide	6(14.30)	1	1	10	10.00
Low dose aspirin	11(26.20)	1	1	4	4
Drug combinations					
4 drugs			1(2.4)		
3 drugs			24(57.20)		
2 drug s			8(19.0)		
Monotherapy			1(2.4)		

TABLE 8: COST OF DRUG THERAPY FOR PATIENTS AT END OF STUDY

Drug combination	Cost per week / patient N*	Cost per month / patient N*
Amlodipine/ lisinopril / co amiloride	270	1080
Methyldopa, Lisinopril, Amlodipine / Co amiloride	590	2360
Atenolol/ Lisinopril / Amlodipine	410	1640
Nifedipine/ Lisinopril / Co amiloride	380	1520
Co- amiloride	70	280

*N= Naira, 1 US $ = N400.00

DISCUSSION: The gender, alcohol consumption, tobacco use and physical activity pattern of high risk community dwellers was similar to that of the source population. The predominance of the 51-60 years age group followed by the above 70 age group can be explained by the fact that blood pressure rises with increasing age [15] and that risk charts employed for this study classifies most persons above 70 years as in the high risk category.

Clinical Characteristics of Subjects: The clinical characteristics evaluated were systolic and diastolic blood pressures, total non- fasting cholesterol, heart rate, body mass index, random blood sugar, waist circumference and cardiovascular risk category. Of these, only systolic and diastolic blood pressures showed significant reductions at the end of study. There was a significant reduction in mean fasting blood sugar level although this was not clinically significant as both values were within normal limits. Overall, other clinical variables did not show any significant differences between baseline and end of study. This profile suggests that the main determinants of cardiovascular risk in this community were age and blood pressure levels. Systolic blood pressure has been shown to be significantly associated with high risk category in both males and females in the general population [16-

[17] and in the elderly [18]. Future interventions in this community should therefore focus more on blood pressure control.

Although there were subjects with high values of all the other variables measured both at the baseline and end of study, the proportion was small and did not contribute significantly to the overall mean. The fact that there were appreciable differences in the upper limits of the 95% confidence intervals for total cholesterol, heart rate and waist circumference at end of study compared to baseline may suggest that extending the duration of intervention might have produced statistically significant differences.

All the subjects received their prescribed medications at the end of the study. Majority were on 2 or 3 drug combination therapy for hypertension at the end of study. For patients at high risk of cardiovascular events, combination therapy with at least 3 drugs has been shown to effectively reduce blood pressure and ensure positive cardiovascular outcomes [19 - 20].

CONCLUSION: Pharmacist's intervention resulted in significant improvements in some clinical characteristics and lowered cardiovascular risk among rural community dwellers. This might suggest that community pharmacists could play a more significant role in cardiovascular risk reduction. The limitations of this study include the fact that the WHO / ISH risk assessment charts may underestimate risk in specified population groups including very obese patients, elderly female population and persons already on antihypertensive medications. Also a longer duration of intervention might have impacted better on measured clinical characteristics.

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CONFLICT OF INTEREST: The authors confirm that there is no conflict of interest associated with this work.

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