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Evaluation of the frequency of use of herbal drugs with concomitant administration of highly active antiretroviral therapy and its effect on medication adherence in two health care facilities in south western Nigeria

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The aim of this study was to evaluate the prevalence of the concomitant use of herbal medicine and anti-retroviral drugs in people living with HIV/AIDs and to evaluate the reasons given by the patients for concomitant administration of highly active antiretroviral therapy (HAART) with herbal drugs in order to establish a possible link between the use of herbal medicines and adherence. A cross sectional study design was utilized via systematic sampling for recruitment of HIV positive individuals receiving their medications in Amuwo-Odofin and Ojo areas in Lagos, Nigeria. Based on the inclusion criteria, 351 HIV positive patients were recruited into the study from the HIV outpatient clinics of two hospitals and had the questionnaires administered to them. 42.7% of the respondents stated that they use herbal medicines. The association for each of the herbal medicines with side effects experienced with the use of ARVs was statistically significant upon cross-tabulation and was a major predictor of herbal drug use. The prevalence of herbal drug use in patients who were adhering to HAART medication was not significantly different from those who were not adhering to medication (p = 0.75 and χ^2 = 6.902). The use or lack of use of herbal medicine is not a determinant for adherence. The most profound reason for herb use was to improve treatment. However, herb/drug interaction studies are imperative to ascertain if interactions occurring are beneficial or harmful. The pharmacist must counsel and re-counsel patients on HAART, not to use herbal products with their antiretroviral medications to avoid drug-herb interactions which could be potentially life threatening.

Key words: Highly active antiretroviral therapy (HAART), herbal drugs, adherence.

INTRODUCTION

World Health Organization (WHO) estimates show that 33.4 million people globally were living with HIV/AIDS and there were 2.0 million AIDS-related deaths in 2015 (WHO, 2015). In sub-Saharan Africa, 22.4 million adults

and children are currently living with HIV/AIDS, representing more than 60% of the global burden of the disease. Nigeria, the most populous country in Africa, is estimated to have about 5 million of the population infected with human immunodeficiency virus (HIV), making it the third largest population in the World infected with the dreadful virus (WHO, 2015).

HIV, caused by the retrovirus is not just a health problem but also a socioeconomic issue as it affects the working population (18-45 years of age) and sexual intercourse mainly is the route of transmission (Wanyenze et al., 2011). Nigerians have a firm belief in the use of herbal remedies for major illnesses (Anabwani and Navario, 2005). HIV infection has no cure medically; hence, this serves as a catalyst to source for cure in herbal remedies (Anabwani and Navario, 2005). Since confirmation of the HIV infection in Nigeria in 1987, after identification of the virus in the 1980's, herbal therapists in Nigeria have been searching for the cure (Abalaka, 2004). This led to many claimed curative medicines or vaccines emanating from Nigeria (Abalaka, 2004). The safety of herbal remedies had been a major concern to health care practitioners especially when the chemical constituents of the product are not known.

According to the World Health Organization, herbal remedies are herbs, herbal materials, herbal preparations and finished herbal products, used to treat a multitude of ailments throughout the world (Amira and Okubadejo, 2007). There are many classes of herbal remedies used for HIV infection based on their chemical constituents such as: alkaloids, carbohydrates, coumarins, flavonoids, lignans, phenolic, proteins, quinones, terpenes and tannins. There are many herbal remedies that are being used in Nigeria for HIV infection. Many of these herbal remedies are used as complementary therapy to HAART; thus, necessitating toxicological studies to be carried out on some herbal products in Nigeria using varying models (Abere and Agoreyo, 2006).

Unlike the assumptions that herbal remedies are harmless because of the natural source, many have been found to be toxic (Chatora, 2003; Cos et al., 2004). Thus, safe herbal remedies are being identified and their use is encouraged, while the use of harmful herbal products is discouraged (Hanapi et al., 2010). Unfortunately, many consumers do not know which herbal remedies are safe, thus the general acceptance or rejection of the herbal products (Hanapi et al., 2010). It was estimated that over 70% of HIV patients taking herbal remedies denied taking them when asked by medical practitioners (Hanapi et al., 2010). This denial by HIV patients may constitute a deterrent to the medical practitioners in early detection of

possible negative drug interactions that could occur with orthodox medicines especially HAART. Traditional herbal medicine has become more popular among HIV/AIDS patients as adjuvant therapy to reduce the adverse effects of HAART (Zhang et al., 2011). Regardless of the subsidized and physical availability of the HAART, majority of Africans living with HIV/AIDS resort to adding to their HAART, traditional herbs e.g. bitters and other herbal mixtures because they either lack the financial means to enable them access the drugs or cannot bear the side effects related to these drugs or believe that there is need for an additional therapy that can permanently cure them of the disease. Concomitant uses of HAART with some herbal remedies with high antioxidant content have been reported to be beneficial in the treatment of oxidative stress amongst some HIV infected individuals (Sharma, 2014). Negative drug interactions between some herbs like garlic and St John's Wort with HAART have been established (Hsiao et al., 2003; Zhang et al., 2011). African potato *Hypoxis* spp. and *Sutherlandia frutescens* have caused potential harmful interactions with anti-retroviral drugs (Blench, 2006).

The study therefore aims at studying the prevalence of the concomitant use of these herbal mixtures like bitters containing different herbs, Ginger, Moringa, locally brewed concoctions generally termed "*agbo*" with HAART and the effect it has on adherence and also evaluate the reasons for the concomitant administration of HAART with these herbal drugs in western Nigeria.

METHODOLOGY

Study site

Data collection was done between November 2015 and January 2016 at two ART clinic sites in Lagos State being Holy Family Catholic Hospital Festac town Amuwo Odofin Local government area and the Olusola Ojo Primary Health Center, Ojo Local Government Area both in Lagos Western Nigeria. The former is a faith-based hospital in an urban area; the latter center is situated in a semi-urban area and is a government hospital. Both centers are well equipped with adequate staff to run the following HIV related programmes; Prevention of mother to child transmission (PMTCT), HIV testing and counselling and HIV care via provision of HAART.

Study population and study design

Only one treatment subgroup was utilized, that is, only patients on HAART were interviewed. A cross sectional study design was utilized via systematic sampling for recruitment of HIV positive individuals. The inclusion criteria was being a HIV positive adult between 18 and 60 years and being on HAART, receiving these

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medications at one of the study centers used for this study. During the clinic days, the staff attending to the patients asked every second male and female if they would be interested in participating in this research, where a positive response was obtained and the patient met the inclusion criteria he was directed to a research assistant who then furnished the patient with more information and the study consent. An interviewer questionnaire was used and prevalence of concomitant administration of HAART, with herbal drugs determined.

Sample size calculation was based on the assumption that 75% of the Nigerian population utilizes herbal drugs in one form or the other (Bamidele et al., 2009; Abere and Agoreyo 2006). The level of significance utilized for this study was 0.05 and a power of 0.75 was obtained based on the assumption of the number of Nigerians using herbal medicines. Utilizing sample size calculator NSS version 12.0 (2013), Australian Bureau of Statistics, a sample size of 351 was obtained.

HIV positive patients receiving HAART were treated according to the National guidelines of the Federal Ministry of Health and the National Agency for the control of AIDS in Nigeria. Fixed dose combinations (FDC) for First line treatment comprised of Lamivudine/Zidovudine and Nevirapine (FDC) or Lamivudine/Tenofovir and Efavirenz (FDC). FDC for second line treatment comprised of Atazanavir-Ritonavir/Lamivudine/Tenofovir or Lopinavir-Ritonavir (Alluvia®)/Lamivudine/Tenofovir. These were the combinations utilized by patients in this study.

Data collection instrumentation

The material/instrument used was the semi-structured questionnaire combining closed and open-end questions. The questionnaire contained two sections; personal information and the other section contained questions directed at determining the prevalence of concomitant administration of HAART and herbal drugs/traditional and complimentary medicines. The questionnaires were first pretested using 10 HIV positive patients not enrolled in the study, the interview lasted an average of 17 min. With the aid of an interpreter, verified by another translator, individuals who do not speak English were attended to in the language they felt most comfortable with. At the start of the study, a randomized sample of 20 respondents underwent a test – retest procedure to assess the reliability of questionnaire responses. An 8-day time interval was given for the re-test to ascertain the reliability of the questionnaires.

Data analysis

Statistical analysis was carried out using the Chi-square tool of SPSS version 21.0 with a p < 0.05 level of significance.

Study approval and ethics consideration

The Lagos University Teaching Hospital Research Ethics Committee of the College of Medicine University of Lagos provided ethical approval for the study (CM/HREC/02/16/002). Approval was also obtained from the medical directors of the institutions utilized as HIV/AIDS treatment sites. Each participant was duly informed of the study and asked to sign consent forms. Participant's identities were kept anonymous after identification numbers were assigned to each participant.

RESULTS AND DISCUSSION

Based on the inclusion criteria for the study, 351 HIV positive patients were recruited into the study. Within the study sample, 52.7% of the respondents stated that they do not use herbal medicines, while 42.7% stated that they use herbal medicines despite being asked not to do so prior to commencing antiretroviral treatment. Traditional extract known in Yoruba language as *agbo* was the most commonly used herbal medicine. The frequency ranking for the other herbal medicines was bitter leaf>holy water>ginger> Moringa infusion>bitters as shown in Figure 1. 44.1% of the respondents stated that their reason for using herbal medicines was to improve treatment while 12.5% of the respondents stated that they were given these herbal mixtures by family and friends to take because of the chronic nature of the disease they were battling with (Figure 2). The association between socio-demographic characteristics and the use of herbal medicine was not statistically significant (Table 1). Table 2 shows a statistically significant association between the knowledge of the use of herbal medicines and the use of herbal medicines. Cross-tabulation of each of the side effects experienced by respondents as a result of the use of their ARVs and use of herbal medicines showed that there was no statistically significant relationship amongst those that experienced bad dreams, weight loss and vomiting and the use of herbal medicines.

The use of herbal remedies has been extensively studied in Nigeria among varying demographics; pediatrics, diabetics, sickle-cell anemia patients and terminally ill patients suffering from malignancies as well as in the general population (Oreagba et al., 2011). Herbal medicine use varies form 27.95% to as high as 72.43% in some demographics studied (Oreagba et al., 2011). There has been paucity of data documenting herbal drug use among retroviral positive patients especially because these groups of patients are usually asked not to co-administer these medicines with their antiretroviral drugs. The prevalence of herbal drug use in this study was 47.3% without any significant difference in the pattern of use between males and females p = 0.88 and $\chi^2 = 2.902$ (Table 1).

Out of 351 HIV-infected persons recruited into the study, there were more females (72.4%) than males (27.6%) and more employed people (69.2%) than unemployed people (30.8%). Majority of the respondents (68.9%) were within the age group of 25-45 years. Overall, most of the participants had attained at least secondary level of education while a small proportion of respondents (5.1%) had no formal education. There was no statistically significant association between socio-demographic characteristics (gender, age, employment status and level of education) and the use of herbs. Similar results were obtained where it was reported that having a rural dwelling, female gender, older age, a lack of formal education, not being married, having employment and haven been HIV positive for less than
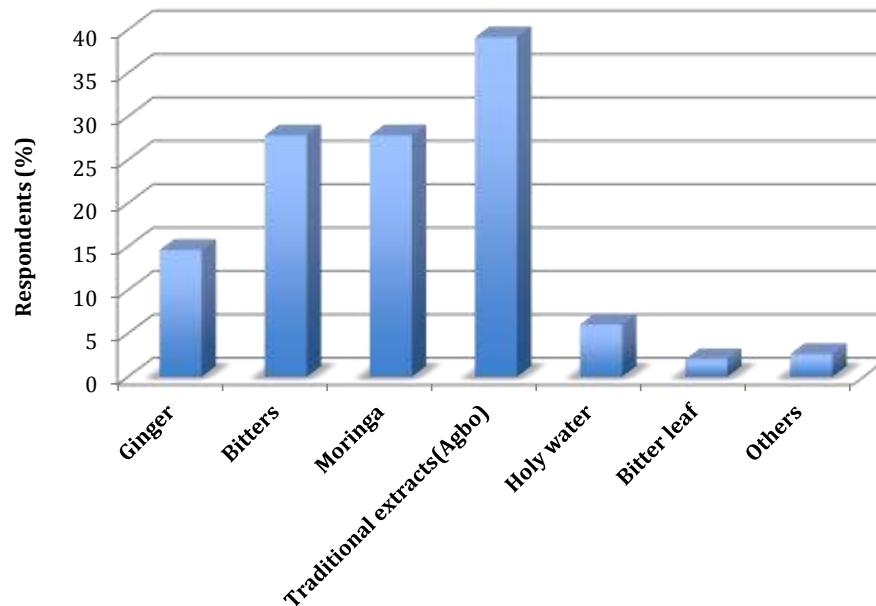
Figure 1. Frequency distribution of herbal medicine utilized by the population examined.

5 years were all predictors of traditional medicine use amongst people living with AIDS (Oreagba et al., 2011; Hughes et al., 2012).

Traditional herbal medicine was not commonly used by the study respondents, with 185 (52.7%) of the respondents claim that they do not use herbal medicines. This response may be premeditated and could be due to instruction from the pharmacist that they will be denied access to HAART if they did use them concurrently with herbal products. This instruction given by the pharmacist is as a result of known interaction between herbal medicines and antiretrovirals (Hanapi et al., 2010). The findings from this study shows that a greater proportion of the respondents do not use complementary herbal medicines with ARVs. This observation is contrary to the earlier report of Duggan et al. (2001) that reported 67% of a group of examined students concurrently used herbal medicine with antiretrovirals. The low proportion of respondents that use herbal medicines obtained in this study may be due to the continuous adherence to the counseling offered to patients to avoid taking herbal medicines with ARVs because of potential interaction and adverse effects. The association between knowledge of the use of herbal medicine and the actual use of herbal medicine was significant with 51.7% of the respondents who used herbal medicines reporting they had been advised not to do so by the pharmacist as shown in Table 2. This could also be due to the influence of family, friends and prevalence of advertisements in the media that herbal remedies have potentials in combating all forms of ailments.

However, among those who reported that they use herbal medicine, traditional extracts (agbo) were the most commonly used herbal medicine, used by 109 (31.1%) of the respondents. This finding compares favorably with earlier studies (Oreagba et al., 2011; Hughes et al., 2012). This is probably due to the belief of these individuals that the different constituents in the 'agbo' are able to bring them speedy healing.

Majority of the respondents (44.1%) stated that their reason for using herbal medicines was to improve treatment (Figure 2). Also, majority (66.1%) of the respondents stated that a pharmacist/pharmacy attendant/counselor spoke to them about the use of herbal drugs.

As regards side effects, majority (68.9%) of the respondents stated that they do not experience side effects from the ARVs they were using. However, for those that stated that they experienced side effects, majority (14%) stated that they experience side effects other than bad dreams, anaemia, blurred vision, weight loss, weight gain and vomiting. Some side effects characteristic of ARVs includes vomiting (Tenofovir, Zidovudine, Efavirenz), anaemia (Zidovudine), rashes (Nevirapine), diarrhoea (Abacavir), bad dreams (Efavirenz). These side effects may not necessarily be as a result of the herbal medicines used. On the other hand, some herbal medicines may cause side effects such as nausea and vomiting (bitters), skin irritation, heartburn (ginger), paralysis (root extract of *Moringa Oleifera*) (Sharma 2011 et al., Amzat and Abdullahi 2008). There was a statistically significant association between side
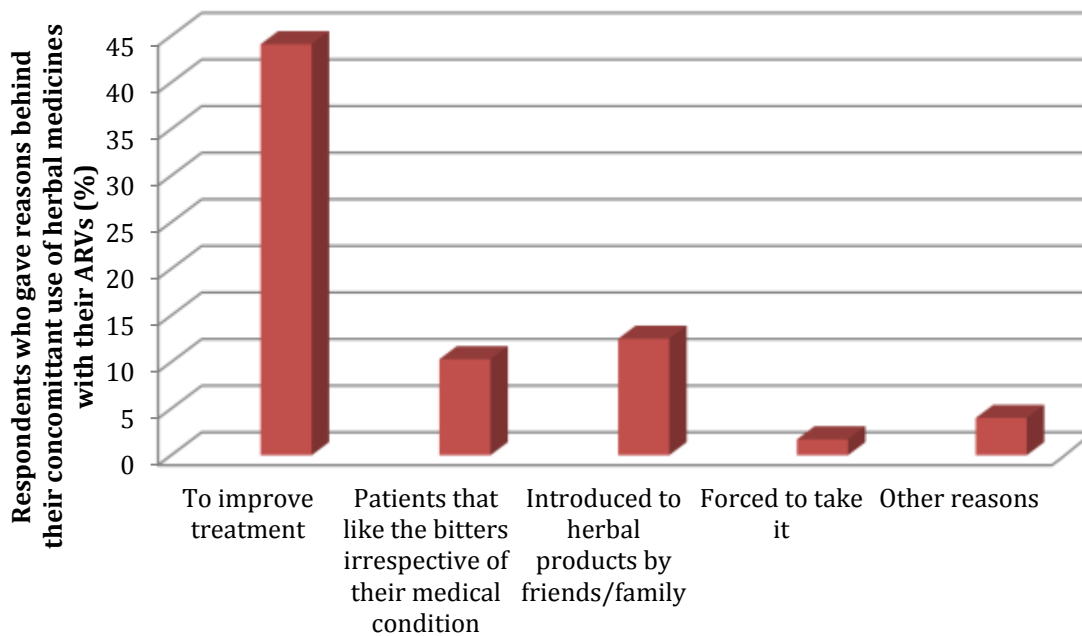
Figure 2. Reasons given by respondents for concomitant use of antiretroviral treatment with herbal medicines.

Table 1. Association between socio-demographic characteristics and use of herbs.

Variable	Use of herbs			
	Yes	**No**	**Total**	
Gender				
Female	113 (44.5%)	141 (55.5%)	254	χ^2 = 2.902
Male	53 (54.6%)	44 (45.4%)	97	P = 0.88
Total	166 (47.3%)	185 (52.7%)	351	
Employment Status				
Employed	118 (48.6%)	125 (51.4%)	243	χ^2 = 0.508
Unemployed	48 (44.4%)	60 (55.5%)	108	P = 0.476
Total	166 (47.3%)	185 (52.7%)	351	
Age				
15-24 years	18 (51.4%)	17 (48.6%)	35	χ^2 =4.418
25-45 years	121 (50.0%)	121 (50.0%)	242	P = 0.110
46-60 years	27 (36.5%)	47 (63.5)	74	
Total	166 (47.38%)	185 (52.7%)	351	
Level of education				
Primary	29 (50.9%)	28 (49.1)	57	χ^2 = 0.809
Secondary	84 (47.2)	94 (52.8)	178	P = 0.847
University	46 (46.9)	52 (53.1)	98	
No formal education	7 (38.9)	11 (61.1)	18	
Total	166 (47.3)	185 (52.7)	351	

No significant association between socio-demographics of respondents and their herb usage.

Table 2. Association betw een know ledge of the use of herbal medicine and the use of herbal medicine.

Knowledge of the use of herbal medicine			Use of herbal medicine		Total
			Yes	No	
YES		Count	120	112	232
		% within	51.7%	48.3%	100.0%
NO		Count	46	73	119
		% within	38.7%	61.3%	100.0%
Total		Count	166	185	351
		% within	47.3%	52.7%	100.0%

			*Chi-square tests		
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-square	5.389[a]	1	0.020	-	-
Likelihood ratio	5.427	1	0.020	-	-
No. of valid cases	351	-	-	-	-

*Chi square test indicates significant association betw een know ledge of the use (w hether respondents had been informed about not using HAART w ith herbal medicine) and the actual use of herbal medicine.

effects and the use of herbal extracts. This can be explained by the fact that traditional extracts contain a variety of active constituents and so the actual constituent causing the side effect may be unknown.

Adherence plays a vital role in the treatment outcome of retroviral positive patients as patients that adhere to their medications are likely to retain their CD4 at higher than 200 cells/mm^3 and enjoy a good quality of life as shown in Table 3. The prevalence of herbal drug use in patients who were adhering to HAART medication was not significantly different from those who were not adhering to medication, p = 0.75 and χ^2 = 6.902. The use or lack of use of herbal medicine was therefore not a determinant for adherence. The respondents were acutely aware of the need for them to adhere to HAART, as such; only 4.8% of the respondents who stated that they had missed more than one dose of their ARVs in the past month stated they forgot to take their medications. The level of adherence among the population studied was very high with 90.4% stating that they had not missed a dose in 3 months, this was associated with the caregivers and support group's periodic counseling on the need for drug adherence to prevent patients from having opportunistic infections like tuberculosis.

Most of the respondents (4.8%) who stated that they had missed more than one dose of their ARVs in the past month stated that the reason was that they ran out of pills. This may be untrue, as the pills are given to patients for free and can be explained by the patients resorting to using herbal medicines. Similar studies carried out by Peltzer et al. (2008) and Banda et al. (2007) have shown that patients using herbal treatments in conjunction with

ART are more likely to take gaps in treatment or reduce their level of adherence. Also, majority of the respondents (66.1%) stated that they are not part of a support group. Being part of a support group has been shown to encourage adherence to antiretroviral therapy. 69.5% respondents with CD4 count > 200 cells/mm^3 were more in this study with majority (44.3%) claiming that they do not use herbal drugs while majority of the respondents with CD4 count less than 200 cells/mm^3 (44.5%) state that they use herbal drugs (Table 3). This finding is similar to that of a 2008−2011 study in Kampala, Uganda where Wayneze et al. (2011), found that patients who had reported receiving treatment from traditional healers or other informal sources had lower CD4 counts at treatment initiation. However, the association between CD4 count and the use of herbal drugs was not statistically significant.

A greater percentage of respondents (60.4%) with poor quality of life use herbal drugs, as compared to those with good and very good quality of life, respectively (Table 3). This could be due to the fact that they felt the use of herbal drugs complemented the ARVs thus making it more beneficial to their wellbeing. The association between use of herbal drugs and overall quality of life was statistically significant with p = 0.058 and χ^2 = 0.902.

According to estimates by World Health Organisation (WHO) and Joint United Nations Programme on HIV and AIDS (UNAIDS), 36.9 million people were living with HIV globally at the end of 2011 (WHO 2011). That same year, some 2 million people became newly infected, and 1.2 million died of AIDS related causes. With more than 34 million infected individuals, the prevalence of Human

Table 3. Evaluation of the interaction of variables influencing herbal drug use and its implication on adherence.

Variable	*Percentage (%)
Do you use herbal drugs?	
Yes	47.3
No	52.7
How often do you use herbal drugs?	
Never	52.4
Daily	4.6
Weekly	16.0
Monthly	15.1
One a year	8.5
Cannot remember	3.4
Which herbal medicines do you use?	
Ginger	9.7
Bitters	18.8
Traditional extracts (agbo)	15.4
Holy water/spiritual healing/prayers	31.1
Bitter-leaf	4.0
Others	
Why do you use herbal medicines	
To improve treatment	33.6
Because I like it	10.5
It makes me feel better	10.3
I was forced to take it	1.7
It was introduced to me by friend/family	12.5
others	4.0
Did a pharmacist/pharmacy attendant/counsellor talk to you about the use of herbal medicines?	
Yes	66.1
No	33.9
Do you experience side effects from the antiretrovirals?	
Yes	30.8
No	68.9
New comer	0.3
Side effects from antiretrovirals experienced	
Bad dream	6.0
Blurred vision	5.7
Anaemia	8.5
Weight gain	1.7
Weight loss	4.3
Vomiting	6.3
Others	14.0
Reason for missing more than one dose of ARV in the past month	
Away from home	4.3
Wanted to avoid side effects	2.3
Felt sick/ill	1.4

Table 3 cont'd

Felt good	**0.0**
Had too many pills to take	0.9
Busy with other things	2.6
Ran out of pills	4.8
Fell asleep/slept through dose time	2.3
Had problems taking pills at specified times	0.6
Simply forgot	4.3
Felt depressed/overwhelmed	2.6
Felt like the drug was toxic/harmful	0.0
Had a change in daily routine	0.9
Did not want others to notice	1.4
CD4 count	
>200	69.5
<200	28.8
Newly screened	1.7
Are you part of a support group?	
Yes	32.8
No	66.1
HIV staging	
STAGE 1	46.7
STAGE 2	32.8
STAGE 3	16.5
STAGE 4	4.0
Overall Quality of Life	
Very poor	1.1
Poor	13.7
Good	73.5
Very good	11.7

*% Values signify frequency of occurrence of variables as indicated by respondents.

Immunodeficiency Virus (HIV) infection remains a perturbing pandemic that has been projected to be one of the most serious significant public health concerns. Nonetheless, the introduction of HAART has significantly reduced AIDS related morbidity and mortality rate. Although, the quality of life of those infected have been improved, patients continue to experience physical and emotional discomforts due to the infection and/co-infection and related treatment and this could be one of the reasons they resort to using herbal medicines (Oreagba et al., 2011). The use of herbal medicines is viewed to be without risk by patients due to their ethnobotanical origins. It is for this reason that respondents still utilize these herbal products even when advised not to do so by their health care givers. Drug-herb interactions occurring from this concomitant administration may be under reported, as patients do not readily disclose to physicians or pharmacist the complimentary/ alternative therapies they are using. The proliferation of registered herbal products has generated a lot of public awareness and has brought about the need for regulation of the doses of these herbal remedies to prevent herbal medicine toxicity. Patients suffering from chronic illnesses which have no cure are especially attracted to herbal medicines; hence, the formulation of herbal medicines into metered dosage forms can be beneficial in terms of detecting the actual or approximate amounts of active ingredients of herbal medicines that may be toxic; thus, creating a safety profile for them. Studies have shown the presence of heavy metals in the traditionally prepared herbal medicines locally called *agbo,* which may subsequently have adverse interaction

with HAART and affect patient overall well being, the very parameter which was the main reason why the 44.1% respondents opted to take the herbal medicines.

Conclusion

The use or lack of use of herbal medicine was not a determinant for adherence. The respondents who used herbal medicines concomitantly with HAART did so because they believed that it improved their treatment. The authors recommend herb/drug interaction studies in order to ascertain if interactions that occur between HAART and herbs are beneficial or harmful. Since this information is not yet available, the pharmacist must counsel and re-counsel patients on HAART not to use herbal products concomitantly with their antiretroviral medications to avoid drug-herb interactions which could be potentially life threatening.

Conflict of interest

The authors have not declared any conflict of interest.

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