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Knowledge, Attitude and the Use of Patient Package Inserts: Perspectives on Adherence to Antiretroviral Therapy

B. N. Joseph[1*], M. N. Nyam[1], B. M. Aya[1], U. O. Asiegbu[1], J. Bulus[2], D. M. Umar[1], S. I. Joseph[3], P. A. Damun[1], D. W. Dayom[1] and M. L. P. Dapar[1]

[1]Department of Clinical Pharmacy and Pharmacy Practice, University of Jos, Jos, Nigeria.
[2]Plateau State Specialist Hospital, Jos, Nigeria.
[3]Medical Pharmacy Unit, Pharmacy Department, Jos University Teaching Hospital (JUTH), Jos, Plateau State, Nigeria.

Authors' contributions

This work was carried out in collaboration between all authors. Author BNJ conceived and designed the study, wrote the protocol and the first draft of the manuscript. Author MNN wrote part of the protocol, conducted literature search and collected the data. Author BMA performed the statistical analysis. Author UOA managed the literature search and data collection. Author JB reviewed the design. Authors DMU and SIJ wrote part of the discussion. Authors PAD and DWD reviewed the manuscript. Author MLPD reviewed the instrument and statistical analysis. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: Patient package insert is an innovative tool capable of providing additional medication information in written form; it has the potential to promote adherence to antiretroviral medicines.
Objectives: This study assessed the knowledge of respondents on antiretroviral medicines. It determined the proportion of clients who read the Patient Package Inserts (PPIs) for antiretroviral medicines. The study assessed the impact of using the Patient Information Leaflets (PILs) on adherence to antiretroviral therapy.

**Corresponding author: Email: jbnasara2002@yahoo.com, josephb@unijos.edu.ng;*

Methods: A cross-sectional design involving simple random sampling was employed. The study recruited 404 participants from the HIV/AIDS centres of Bingham University Teaching Hospital (BHUTH) and Plateau State Specialist Hospital (PSSH), Jos, Nigeria. Pre-tested structured questionnaires were administered to participants. Data was analysed with the Statistical Package for the Social Sciences version 20.0 and $p \leq 0.05$ was considered statistically significant. Results were presented in descriptive and inferential statistics.
Results: The study revealed that 36.1% of the respondents read the patient package inserts. Reading the package inserts was statistically associated with educational status (p=0.000), marital status (p=0.022), occupation (p=0.000), gender (p=0.000) and religion (p=0.000). Adherence in the last one week significantly correlated with age (p=0.048) and marital status (p=0.002). One-third of the respondents had good perception about patient information leaflets. Using the leaflets had no statistically significant implication on adherence to antiretroviral medicines.
Conclusion: The study found poor usability of the patient package inserts among HIV/AIDS clients; although, the adherence level among the clients was quite high.

Keywords: Knowledge; attitude; use of patient package inserts; adherence; antiretroviral therapy.

1. INTRODUCTION

Patient Package Inserts (PPIs) are printed leaflets that contain information based on regulatory guidelines for the safe and effective use of drugs [1]. Patient package inserts are unbiased, evidence-based, critically evaluated information aimed at educating and empowering the consumers to make informed decisions about their medications [2]. The relevance and effectiveness of PPIs in promoting medicines knowledge have been widely reported [3,4]. However, it is dependent on the extent to which the PPIs are read and the degree to which patients understand them [5]. Reading the leaflets was associated with the nature of the disease; patients read the leaflets for chronic diseases more than those for acute diseases [5]. Drug information on labels and package inserts is a major source of knowledge for patients as they attempt to balance the risks and benefits of drugs and to administer them safely; however, this information is often inconsistent, incomplete and difficult for patients to read and understand [6,3,7].

Reading the PPIs has been shown to stimulate anxiety and this was statistically associated with poor adherence [5]. While the patient deserves the right to be adequately informed about the effect of the medications on his/her health; such information may cause agitation, fear and discomfort capable of promoting non-adherence.

This study assessed the knowledge of respondents on antiretroviral medicines. It determined the proportion of clients who read the PPIs for antiretroviral medicines. The study assessed the impact of using the PPIs on adherence to antiretroviral therapy.

2. METHODS

The research was conducted in two tertiary hospitals namely: Bingham University Teaching Hospital (BHUTH) and Plateau State Specialist Hospital (PSSH), Jos, Nigeria. Both facilities offer antiretroviral therapy (ART) based on the exemption policy. The study was a cross-sectional survey of HIV/AIDS positive patients 18 years of age and older accessing antiretroviral therapy. With an estimated 10,000 patients accessing care in both Bingham University Teaching Hospital and Plateau State Specialist Hospital, we calculated a sample size of 392 which was adjusted to 410 to account for attrition; however, 404 questionnaires were filled and returned. The study employed simple random sampling. A self-administered questionnaire was distributed to participants during routine clinic visits. The questionnaire had four (4) domains: the first was the socio-demographic data, the second domain had themes on knowledge, awareness and attitude about ART medications, the third consisted of views and opinions of respondents on PPIs while the fourth domain comprised the simplified medication adherence questionnaire developed by Knobel et al. [8]. In this study, adherence was predicated at achieving ≥95% intake of the total doses prescribed in the last one week as well as the last three months. The research was conducted from 20th September 2015 to 21st March, 2016. We used the Statistical Package for the Social Sciences (SPSS) for analysis. Chi-square test was used to compare socio-demographic variables with adherence and

reading of PPIs. Results were presented as descriptive and inferential statistics.

The protocol for this research was presented to the Ethics and Research Committees of Bingham University Teaching Hospital and Plateau State Specialist Hospital, Jos, Plateau State. The approval from BHUTH was dated 17th September, 2015, reference number NHREC/21/05/2005/00161 and that from PSSH was dated 23th September, 2015.

3. RESULTS

3.1 Demographics

This study recruited 404 respondents. Majority of the respondents, 94 (23.3%) were within the age group of 30-35 years. Females accounted for 70.3% of the respondents. Majority of the participants were married (66.1%), singles constituted 15.1%; 6.4% were either divorced or separated while widowed represented 12.4%. Almost all the respondents (92.8%) were Christians. About 2/5 of the respondents (38.9%) went to secondary school, more than one-quarter (26.2%) had tertiary qualification while participants who cannot read or write accounted for 10.4% (Table 1).

3.2 Knowledge and Awareness about Antiretroviral Medication Use

Majority (94.1%) of the respondents recalled the daily frequency of their antiretroviral therapy (ART) while 61.4% remembered exactly the name of the antiretroviral therapy (ART) they were using. About two-thirds (65.8%) of the participants admitted antiretroviral medications were associated with certain adverse effects. Majority (82.2%) of the respondents understood the relevance of ART medicines.

3.3 Reading the Patient Package Inserts

A total of 146 (36.1%) read antiretroviral therapy (ART) leaflets. About one-thirds (31.4%) of the respondents who read the leaflets wanted to learn everything about the drugs while very few (1.7%) respondents sought to know the side effects associated with ART medicines. Illiteracy was reported as the major reason for not reading medication information leaflets (17.8%); 46 respondents (11.4%) admitted the leaflets were bulky, 10.6% never knew its relevance while 7.7% believed leaflets were not comprehensible. Majority (92.6%) of the respondents obtained additional information about their ART medicines from health professional (Table 2).

3.4 Respondents' Adherence Status

The study indicated that 89.9% of the participants reported adherence level of ≥95% in the last one week (1 week) while 99.8% attained adherence level of ≥95% over the last three months (3 months) (Fig. 1).

3.5 Chi-square Association between Respondents' Demography and Reading the PPIs

The age group 42-47 years accounted for the highest population that read the PPIs. Reading the PPIs was associated with marital status (*p*-value = 0.022); level of education (*p*-value = 0.000); occupation (*p*-value = 0.000); gender (*p*-value = 0.000) (Table 3).

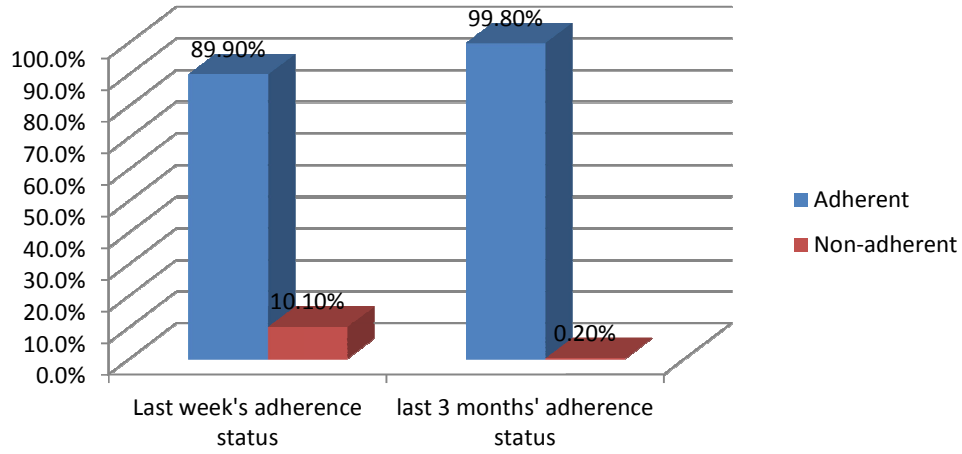

Fig. 1. Respondents' adherence status

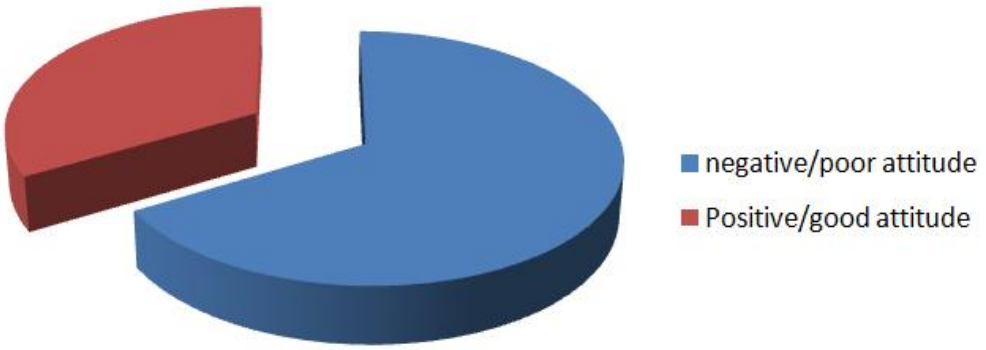

Fig. 2. Respondents' perception on PPIs

3.6 Readership of Patient Package Inserts and association with Adherence

Reading the patient package inserts was not associated with ART medication adherence (Table 4).

3.7 Attitude/Perception on PPIs

One-third of the respondents (33.4%) admitted to having a positive attitude towards the use of PPIs (Fig. 2).

4. DISCUSSION

We found a very high level of adherence to antiretroviral medication among respondents in spite of the fact that only 36.1% of the respondents read the PPIs. An assessment of their adherence status indicated that 89.8% of the participants attained adherence level of ≥95% in the last one week while 99.8% of them achieved ≥95% adherence level over the last three (3) months. Reading the patient information leaflets was not statistically associated with adherence.

Educational status was associated with reading the patient package inserts (*p*-value=0.000); those with tertiary qualification were more likely to read PPIs. This possibly implies that those with higher educational status were more likely to have better health seeking behaviour which includes reading the PPIs to promote their health. This concurs with the findings of Kalichman et al. [9] who asserted that respondents with less than 12 years of education were over three times more likely to be non-adherent than those with higher educational status while those with lower literacy level were nearly four times more likely to be non-adherent than those with higher literacy. The study established that married respondents were more likely to read the leaflets (*p*-value=0.022). This association is probably due to spousal influence and support. While occupation and gender associates negatively with PPIs readership both having *p*-values: 0.000; marital status positively predict PPIs readership (*p*-values: 0.000). This finding concurs with the report of koo et al. [10] who found that occupation correlates with reading PPIs; however, this finding revealed that persons who were self-employed had higher chances of not reading PPIs. Reading culture among Nigerians is quite poor; some read under duress because their work schedules demand so [11].

About one-tenth (7.7%) of the respondents reported that PPIs were incomprehensible and complex. This finding is consistent with the report of Eaton and Holloway [12]. Eaton and Holloway [12] argued that the comprehension of written drug information can be improved by adjusting the readability of informational materials to the reading level of the patients. In Nigeria, it is common knowledge that quite a number of drugs are obtained from foreign countries with their information leaflets written in English or French language. Furthermore, even the indigenous Pharmaceutical companies in Nigeria have failed in their responsibility to present leaflets in at least one of the three major indigenous Nigerian languages. Clients, who cannot read and write in English but can do so in Hausa or Yoruba or Igbo are ironically, out rightly classified as illiterates. In Belgium, Stichelle [13] reported a high readership rate of 89%; this cannot be unconnected to the fact that the regulatory body in Belgium ensured that information leaflets were translated into some major languages in the country. Other barriers to reading the patient

package inserts were illiteracy (17.8%), bulkiness of the package inserts (11.4%) and not knowing the relevance of the leaflets (10.6%). Majority (92.6%) of the respondents admitted they sought for additional information about their medicines and disease conditions from the health workers.

Table 1. Demographic characteristics of participants

Variable	Frequency (N)	Percent (%)
Age		
18-23	5	1.2
24-29	49	12.1
30-35	94	23.3
36-41	84	20.8
42-47	78	19.3
48-53	48	11.9
54-59	26	6.4
>60	20	5.0
Level of education		
Never went to school	42	10.4
Primary school	99	24.5
Secondary school	157	38.9
Tertiary school	106	26.2
Marital status		
Single	61	15.1
Married	267	66.1
Divorced/separated	26	6.4
Widowed	50	12.4
Occupation		
Student	21	5.2
Employed	146	36.1
Unemployed	65	16.1
Self-employed	171	42.3
Gender		
Male	120	29.7
Female	284	70.3
Religion		
Christianity	375	92.8
Islam	29	7.2

N< 404 due to missing values

We found that only 33.4% of our respondents perceived PPIs to be relevant. This implied that this proportion of the respondents was satisfied with the information contained on the leaflets and its potential to improve knowledge and subsequently adherence. This finding concurs with the work of Rajasundaram et al. [14]. These researchers assessed patients' attitude towards information leaflets; they concluded that patients make effort to know about their medicines and medical condition and are willing to spend more time on such issues.

This study recorded good adherence to antiretroviral medicines; this may be attributed to the counselling and awareness sessions provided to patients by the health professionals. Health literacy predicts HIV knowledge and treatment adherence [15]; PPIs provides useful additional information and re-echoes previous cognitive counselling processes [16]. The association between reading the PPIs and adherence however is statistically insignificant implying that reading the leaflets did not influence adherence significantly. This is consistent with similar research conducted in Wessex among diabetics; the researchers found that PPIs were not associated with adherence [17].

Table 2. Distribution of respondents that read the patient package inserts

Variable	Frequency (N)	Percent (%)
Ever read ART medication leaflets		
Yes	146	36.1
No	258	63.9
Information sought		
Everything about the drug	127	31.4
Side effects of the drug	7	1.7
Direction on drug usage	13	3.2
Reason for not reading the leaflets		
Too bulky	46	11.4
Not comprehensible	31	7.7
Cannot read	72	17.8
Font too tiny	19	4.7
Never knew its importance	43	10.6
Others	46	11.4
Obtaining additional information about my drugs		
I ask my physician, pharmacist or nurse	374	92.6
I surf the internet	6	1.5
I visit a drug information centre	2	0.5
I ask my fellow ARV patients	10	2.5

N< 404 due to missing values

Table 3. Chi-square Association between respondents' demography and readership of PPIs

Variable	Read N (%)	Not read N (%)	*p*-value
Age			
18-23	3(2.1)	2(0.8)	0.092
24-29	19(13.0)	30(11.6)	
30-35	26(17.8)	68(26.4)	
36-41	32(21.9)	52(20.2)	
42-47	36(24.7)	42(16.3)	
48-53	19(13.0)	29(11.2)	
54-59	8(5.5)	18(7.0)	
>60	3(2.1)	17(6.6)	
Level of education			
Never went to school	4(2.7)	38(14.7)	0.000*
Primary	20(13.7)	79(30.6)	
Secondary	52(35.6)	105(40.7)	
Tertiary	70(47.9)	36(14.0)	
Marital status			
Single	26(17.8)	35(13.6)	0.022*
Married	104(71.2)	163(63.2)	
Divorced/ Separated	6(4.1)	20(7.8)	
Widowed	10(6.8)	40(15.5)	
Occupation			
Student	15(10.3)	7(2.7)	0.000*
Employed	64(43.8)	82(31.8)	
Unemployed	14(9.6)	51(19.8)	
Self-employed	53(36.3)	118(45.7)	
Gender			
Male	62(42.5)	58(22.5)	0.000*
Female	84(57.5)	200(77.5)	

*N=404, *p≤0.05*

Table 4. Association between PPI's readership status and adherence in the last one week

Variable	Adherent N (%)	Non-adherent N (%)	*p*-value
PPIs readership status			
Yes	127(87.0)	19(13.0)	0.104
No	236(91.5)	22(8.5)	

*N=404, *p≤0.05*

5. CONCLUSION

The study found poor readership of antiretroviral medication leaflets among HIV/AIDS clients; although, the adherence level among the clients was quite high. The study revealed that educational status, marital status, occupation, gender and religion were significantly associated with reading patient package inserts. However, reading the patient information leaflet was not statistically associated with adherence.

6. LIMITATION

We classified those who could read and write in their local languages but not in English as illiterate; these group of people could have benefitted from PPIs if it were presented in their own indigenous languages.

CONSENT

All authors declare that 'written informed consent was obtained from the patient (or other approved parties) for publication of this paper and accompanying images.

ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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