

Research Paper

# Utility of information in package inserts by pharmacists and pharmacy clients in a metropolitan city in Southwest Nigeria

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## Abstract

**Objective** Package inserts provide relevant information to patients and health care professionals on the safety and rational use of drugs. This study evaluated the utility of package inserts by pharmacy clients for information, and by pharmacists during consultation and counselling with patients.

**Methods** This cross-sectional self-administered questionnaire-based study was conducted in Ibadan, Nigeria among 705 pharmacy clients and 344 community and hospital pharmacists. The questionnaire had a 12-item and a 14-item package insert utility scale for pharmacists and pharmacy clients, respectively. The level of utility and association between demographic variables and package insert utility scores were determined with Mann–Whitney *U* and Kruskal–Wallis tests at  $P < 0.05$ .

**Key findings** The response rate was 88.2% for pharmacy clients and 67.2% for pharmacists. Most of the pharmacy clients, 459 (73.8%), check for package inserts in drug packs. The most assessed information in package inserts was dose 432 (69.5%). Some of the pharmacy clients, 276 (44.4%), considered information from health professionals more reliable than that in package inserts. The pharmacy clients' level of education was associated with package insert utility score ( $P = 0.001$ ). Most of the pharmacists, 137 (59.3%), read package inserts but only 36 (15.6%) consulted package inserts during counselling with patients. The pharmacists' age and the number of years spent in practice were significantly associated with package insert utility scores ( $P < 0.05$ ). The level of utility of the information in package inserts by the pharmacy clients and the pharmacists was moderate – 66.8 and 60.0%, respectively.

**Conclusion** Both pharmacists and pharmacy clients use package insert content moderately. Pharmacy clients rely more on information provided by health professionals than the information in package inserts but pharmacists seldom consult package inserts during counselling process.

**Keywords:** package inserts; pharmacists; pharmacy clients; patients

## Introduction

There has been a paradigm shift in the management of patients' health by health professionals from a paternalistic approach to recognising patients' autonomy in the management of their health.<sup>1,2</sup>

<sup>2</sup> This has paved the way for emphasis on evidence-based, patient-centred, accurate and balanced information readily available to patients in the form of package inserts (PIs) to enhance health outcomes. PIs provide relevant information to patients and health care professionals on the safety and rational use of drugs.

Several studies have been conducted on PIs to assess: its completeness, readability and comprehensibility;<sup>[3-5]</sup> its usefulness as a source of drug information,<sup>[6]</sup> attitude of physicians, pharmacists and consumers towards its use<sup>[7, 8]</sup> and the impact of health literacy on its comprehension.<sup>[9]</sup> The findings vary depending on the country of study. Despite the improvement in the design and delivery of PIs based on different studies, they are still fraught with criticisms especially patients' understanding of the content.<sup>[10]</sup>

Pharmacists are the preferred source of drug information to patients<sup>[11, 12]</sup> because of their knowledge, availability and accessibility.<sup>[7]</sup> However, occasionally, inadequate information may be given to the patient by the physician or pharmacist.<sup>[13]</sup> This may lead to communication gap between the patient and the physician and/or the pharmacist. Some patients may resort to getting additional information from

PIs, which may be confusing, scary or misleading;<sup>[14]</sup> for some others, the PI may be non-existent.<sup>[15]</sup>

The physicians or pharmacists who have instructed patients to read PIs or have read PIs with their patients during consultation time are few.<sup>[16, 17]</sup> Information in PIs should complement physicians' and pharmacists' instructions and counselling but their contents should be accurate and regularly updated.<sup>[15]</sup> Since patients or consumers make use of the PIs, it is pertinent for physicians and pharmacists to keep abreast of current drug information in PIs. Although pharmacists get drug information from different sources,<sup>[6]</sup> do they make use of readily available information in PIs during consultation with their patients? This study sought to answer this question and evaluate how pharmacy clients (patients and consumers – PCs) use PIs in a resource-limited setting, like Nigeria.

**Table 1** Socio-demographic characteristics of pharmacy clients and pharmacists

Demographics	Categories	Frequency (%)	Mean ± standard deviation
Pharmacy clients socio-demographic information (N = 622)			
Gender	Male	332 (53.4)	37.74 ± 12.35
	Female	290 (46.6)	
Age (years)	≤28	165 (26.5)	
	29–36	162 (26.1)	
	37–46	143 (23.0)	
	≥47	152 (24.4)	
Religion	Christianity	411 (66.1)	
	Islam	211 (33.9)	
	Traditional	–	
Employment type	Public sector	148 (23.8)	
	Private sector	310 (49.8)	
	Unemployed	164 (25.4)	
Highest level of education	Primary education	71 (11.4)	
	Secondary education	217 (34.9)	
	Tertiary education	237 (38.1)	
	Post-graduate education	97 (15.6)	
Pharmacists socio-demographic information (N = 231)			
Gender	Male	121 (52.4)	33.68 ± 10.24
	Female	110 (47.6)	
Age (years)	≤26	65 (28.1)	
	27–30	59 (25.5)	
	31–40	53 (23.0)	
	≥41	54 (23.4)	
Religion	Christianity	193 (83.6)	
	Islam	37 (16.0)	
	Traditional	01 (0.4)	
Highest academic qualification obtained	First degree only (B. Pharm)	139 (60.2)	
	Postgraduate degree	92 (39.8)	
Year of graduation from pharmacy school	≤3	73 (31.6)	9.63 ± 9.55
	4–5	46 (19.9)	
	6–15	56 (24.2)	
	≥16	56 (24.2)	
Current practice setting	Hospital	112 (48.5)	8.37 ± 9.15
	Community	119 (51.5)	
Number of years spent in current practice setting	≤2	85 (36.8)	
	3–4	37 (16.0)	
	5–12	53 (22.9)	
	≥13	56 (24.2)	

B. Pharm = Bachelor of Pharmacy.

## Methods

### Ethical consideration

Ethical approval was secured from the University of Ibadan/ University College Hospital Ethics Review Committee with the approval number UI/EC/19/0409.

### Study design, setting and participants

A cross-sectional questionnaire-based study was conducted from September to December 2019 in Ibadan, a city located in the south-western part of Nigeria. The participants were pharmacy clients (patients or customers) who purchased drugs from the selected community pharmacies located in Ibadan and pharmacists who practised in hospitals or community settings in the city. Five community pharmacies were conveniently selected based on size and patronage from five local government areas that were randomly selected from the 11 local government areas in the city.

The estimated number of pharmacy clients visiting each of the five selected pharmacies from 16:00 to 19:00 h daily was 150, while the number of community and hospital pharmacists in Ibadan, as of December 2018, was 165 and 179, respectively, as supplied by the secretariat of the Pharmaceutical Society of Nigeria. The sample frame used was 150 pharmacy clients per pharmacy and 344 pharmacists. Based on the estimated sample frames, the sample sizes for pharmacy clients and pharmacists were determined using Taro Yamane's formula with 5% margin of error, and 95% confidence interval.<sup>[18]</sup> The sample size obtained, including 10% provision for

non-response, was 120 pharmacy clients per pharmacy (600 for the five selected pharmacies) and 205 pharmacists.

At each community pharmacy, every third literate pharmacy client, male or female, who was  $\geq 18$  years, and bought at least a drug product was approached. Verbal informed consent was sought before the administration of the questionnaire. Those who gave consent to participate in the study were included. Those who purchased other items other than drugs and those who declined consent to participate were excluded from the study. Those who could not read, understand and be able to fill in the questionnaire written in English language were excluded from the study. Where the client declined consent, the next pharmacy client was approached and the systematic sampling continued until 120–125 clients had been sampled. For the pharmacists, a mail questionnaire survey was conducted.

### Study instrument and data collection

Self-administered structured questionnaires were used for both pharmacy clients and pharmacists. The questionnaires contained questions on demographic information of the participants and a PI utility scale in a Likert format, with 5-graded responses (Never, Rarely, Sometimes, Often and Always). The utility scale for pharmacy clients had 14-items while the one for pharmacists had 12 items. The PI utility scale evaluated the use of PI content by pharmacists for consultations and by patients for information. The pharmacist's questionnaire was designed with an online Google form.

Face validity of the questionnaires was assessed by two clinical pharmacy lecturers versed in the use of questionnaires. The questionnaires

**Table 2** Utilisation of package inserts by pharmacy clients ( $N = 622$ )

Questions	Infrequently $n$ (%)	Occasionally $n$ (%)	Regularly $n$ (%)
How frequently do you check if the pack of the drug(s) given to you contains a package insert or drug leaflet?	35 (5.6)	128 (20.6)	459 (73.8)
How frequently do you use the information contained in package inserts or drug leaflets to take drugs by yourself especially Over-the-Counter (OTC) drugs?	82 (13.2)	181 (29.1)	359 (57.7)
How frequently do you find information in package inserts or drug leaflets unreadable (in terms of lettering or font size, spacing, etc)?	241 (38.7)	248 (39.9)	133 (21.4)
How frequently do you come across technical terms that you do not understand in package inserts or drug leaflets?	132 (21.2)	207 (33.3)	283 (45.5)
How frequently do you consult package inserts or drug leaflets to crosscheck if the drug given to you will work for your illness?	51 (8.2)	176 (28.3)	395 (63.5)
How frequently do you consult package inserts or drug leaflets to know possible side effects that may be experienced with the use of drugs?	111 (17.8)	196 (31.5)	315 (50.6)
How frequently do you consult package inserts or drug leaflets to obtain the right dose?	51 (8.2)	139 (22.3)	432 (69.5)
How frequently do you use package inserts or drug leaflets to know what you are to eat/drink or not to eat/drink when using drugs?	202 (32.5)	195 (31.4)	225 (36.2)
How frequently do you check package inserts or drug leaflets to know the possible adverse drug reactions that may be experienced with the use of drugs?	155 (24.9)	220 (35.4)	247 (39.7)
How frequently do you use package inserts or drug leaflets as a guide on the safety precautions to take when using medicines (e.g. instructions on do not drive or operate machinery because this medicine may cause drowsiness, do not expose yourself to direct sunlight, etc)?	131 (21.0)	211 (33.9)	280 (45.1)
How frequently do you check package inserts or drug leaflets for the proper storage of medicines?	166 (26.7)	199 (32.0)	257 (41.3)
How frequently do you check package inserts or drug leaflets to know when you are not to use a medicine (e.g. don't take if pregnant or lactating, don't take if you are allergic to any of the content of the product, etc)?	170 (27.3)	184 (29.6)	268 (43.1)
How frequently do you check package inserts or drug leaflets to guide you on how to dispose of your unused medicines?	499 (80.2)	66 (10.6)	57 (9.2)
I consider information obtained from healthcare professionals as the most reliable on medicines compared to those in package inserts or drug leaflets.	127 (20.4)	219 (35.2)	276 (44.4)

Regularly (for options 'Often' and 'Always'), Occasionally (for the option 'Sometimes') and Infrequently (for options 'Rarely' and 'Never').

were pre-tested among 25 pharmacy clients in a community pharmacy and 20 community and hospital pharmacists practising outside Ibadan. The pre-test suggested the use of 'drug leaflets' along with 'package inserts' in the pharmacy client's questionnaire. Two ambiguously worded questions were removed from the pharmacist's questionnaire. The internal validity of the two instruments was assessed with Cronbach alpha coefficient to be 0.876 (Pharmacists PI Utility Scale) and 0.795 (Pharmacy Clients PI Utility Scale). The link to the questionnaire for pharmacists was mailed to 344 pharmacists, with the instruction to fill it only once. The pharmacy client's questionnaire was distributed at each pharmacy on a Saturday evening.

The participants' responses were grouped into three utility domains: Regularly (for options 'Often' and 'Always'), Occasionally (for the option 'Sometimes') and Infrequently (for options 'Rarely' and 'Never'). PI utility scores were calculated for pharmacists and pharmacy clients using 11-items (excluding the item 'I consider information obtained from healthcare professionals as the most reliable on drugs compared to those in PIs') and 13 items (excluding the item 'I consider information in PIs as the most reliable'), respectively. The excluded items were not directly related to the frequency of use of the contents of PIs. Subsequently, percent utility of PI was determined as 100 (mean PI utility score) / (maximum PI utility score obtainable). Level of PI utility was described as: low PI utility (0 to ≤50%), moderate PI utility (51 to ≤80%) and high PI utility (81 to 100%).

### Data analysis

Frequencies, percentages, mean ± standard deviation and mean rank were used to summarise the data. Mann-Whitney *U* and Kruskal-Wallis tests were used to determine the differences in the PI utility scores for different categories of socio-demographic characteristics (gender, age, employment types, highest level of education, practice setting, year since graduation and years spent in current practice setting) of the participants. The analysis was conducted with the Statistical Package for Social Sciences Windows version 25 (IBM Corp, USA). The level of statistical significance was set at  $P < 0.05$ .

## Results

Seven hundred and five pharmacy clients were approached, 83 declined consent for the following reasons: 43 were in a hurry, 11 were too sick and 29 could not read in English, the language used for the questionnaire. The response rate was 622/705 (88.2%). One hundred and twelve hospital and 119 community pharmacists filled in the online questionnaire giving an overall response rate of 67.2%.

The male pharmacy clients were 332 (53.4%) and 295 (47.4%) clients were ≥37 years. The average age of the pharmacy clients was  $37.74 \pm 12.35$  years. The majority, 334 (53.7%), had at least tertiary education. The mean age of the pharmacists was  $33.68 \pm 10.24$  years. The community pharmacists, 119 (51.5%), were more than the hospital pharmacists, and 109 (47.1%) of the pharmacists had ≥5 years of practice experience (Table 1).

### Pharmacy clients' utility of PIs

The majority of the pharmacy clients, 459 (73.8%), checked for PIs when they purchased drugs, 432 (69.5%) regularly checked for the appropriate dose and 395 (63.5%) checked if the drug prescribed was for the right indication. Most of the pharmacy clients, 499 (80.2%), do not check the PIs on how to dispose of unused medicines. The order of obtaining information regularly from PIs was dosing > indication > side effects > safety precautions > contraindications > storage condition > adverse drug reactions (ADRs) > disposal of unused drugs (Table 2). There was no difference in gender, age and employment type in the utility of PIs ( $P < 0.05$ ) (Table 4). The pharmacy clients with tertiary or postgraduate education used PIs more than those with primary or secondary education did ( $P = 0.001$ ; Table 4). The level of PI utility among the pharmacy clients was moderate (66.76%).

### Pharmacists' utility of PIs

More than half of the pharmacists, 137 (59.3%), read PIs to acquire necessary information about drugs but few, 36 (15.6%), regularly consulted PIs during counselling with patients. About half of the pharmacists, 117

**Table 3** Utilisation of package inserts by pharmacists ( $N = 231$ )

Questions	Infrequently <i>n</i> (%)	Occasionally <i>n</i> (%)	Regularly <i>n</i> (%)
I read package inserts to furnish myself with necessary information about each drug product.	8 (3.4)	86 (37.2)	137 (59.3)
I check package inserts only during the process of counselling patients.	103 (44.6)	92 (39.8)	36 (15.6)
I consider the information in package inserts as the most reliable.	63 (27.2)	82 (35.5)	86 (37.2)
How frequently do you check package inserts to determine the appropriate indication for a drug?	27 (11.7)	106 (45.9)	98 (42.4)
How frequently do you check package inserts to give dose recommendations?	37 (16.0)	109 (47.2)	85 (36.8)
How frequently do you check package inserts to counsel patients on possible side effects that may be experienced when taking their drug(s)?	65 (28.2)	104 (45.0)	62 (26.8)
How frequently do you check package inserts to counsel patients on possible adverse drug reactions to watch out for?	76 (32.9)	94 (40.7)	61 (26.4)
How frequently do you check package inserts to instruct patients on what to do immediately after they notice any adverse drug reaction?	106 (45.9)	84 (36.4)	41 (17.7)
How frequently do you consult package inserts for contraindications before dispensing a drug?	78 (33.8)	98 (42.4)	55 (23.8)
How frequently do you consult package inserts to advise patients on proper storage of their drug(s)?	106 (45.9)	76 (32.9)	49 (21.2)
How frequently do you consult package inserts for paediatric dosages?	31 (13.4)	83 (35.9)	117 (50.6)
How frequently do you check package inserts to counsel patients on proper disposal of unused medicines?	159 (68.9)	45 (19.5)	27 (11.7)

Regularly (for options 'Often' and 'Always'), Occasionally (for the option 'Sometimes') and Infrequently (for options 'Rarely' and 'Never').

**Table 4** Association of socio-demographic factors of pharmacists and pharmacy clients with package insert utility score

Socio-demographic factors	Categories	Package insert utility score N (mean rank)	P-value
Pharmacy clients			
Gender	Male	332 (316.30)	0.476 <sup>a</sup>
	Female	290 (306.01)	
Age, years	≤ 28	165 (319.60)	0.742 <sup>b</sup>
	29–36	162 (318.63)	
	37–46	143 (302.80)	
	≥47	152 (303.30)	
Employment type	Public sector	148 (314.94)	0.928 <sup>b</sup>
	Private sector	310 (312.10)	
	Unemployed	164 (307.26)	
Education level	Primary education	71 (237.38)	<0.001 <sup>b*</sup>
	Secondary education	217 (303.38)	
	Tertiary education	237 (324.15)	
	Post-graduate education	97 (353.02)	
Pharmacists			
Gender	Male	121 (117.07)	0.797 <sup>a</sup>
	Female	110 (114.82)	
Age, years	≤26	65 (108.10)	0.002 <sup>b*</sup>
	27–30	59 (102.92)	
	31–40	53 (109.73)	
	≥41	54 (145.96)	
Year since graduation	≤3	73 (105.83)	0.001 <sup>b*</sup>
	4–5	46 (119.86)	
	6–15	56 (97.80)	
	≥16	56 (144.29)	
Years spent in current practice	≤2	85 (106.62)	0.003 <sup>b*</sup>
	3–4	37 (106.07)	
	5–12	53 (107.62)	
	≥13	56 (144.73)	
Practice setting	Hospital	112 (113.48)	0.517 <sup>a</sup>
	Community	119 (118.37)	

<sup>a</sup>Mann–Whitney *U* test.<sup>b</sup>Kruskal–Wallis test; \**P* < 0.05.

(50.6%), regularly checked for paediatric dosing in PIs, and 61 (26.4%) of the pharmacists regularly used PIs to counsel patients on ADRs. Table 3 shows that 159 (68.9%) pharmacists do not check PIs on how to counsel patients on proper disposal of unused medicines. The pharmacists ≥41 years, those who graduated ≥16 years ago and those who had spent more than 13 years in their current practice setting had higher PI utility scores than others as shown in Table 4. The level of PI utility among the pharmacists for consultation purposes was moderate (60.01%).

## Discussion

PI is designed to provide up-to-date relevant information on drugs to patients and healthcare professionals in order to optimise therapy. This study examined the use of PIs from the pharmacists and pharmacy clients' perspectives. The results showed that 74% of the pharmacy clients checked their drugs for PI and 59% of the pharmacists consulted PIs to have more information on the drugs. In other studies, the proportion of patients who were aware of, read or checked PIs ranged from 36 to 95%.<sup>[19–23]</sup> Most patients obtained the information required about drugs from PIs,<sup>[19,21]</sup> but not all considered it useful.<sup>[19]</sup> In a related study in Nigeria, 98% of the pharmacists made use of PIs.<sup>[6]</sup> This is higher than the 59% we reported, probably because the former study was conducted in two states in Nigeria while our study was carried out in a state in Nigeria. Less than one-third of the pharmacists checked the PIs for side effects,

ADRs or contraindications before consultations. Diobi *et al.*<sup>[6]</sup> reported similar findings. Reading the PI could enhance pharmacist's professional confidence and practice, and equip the pharmacist with knowledge that may be useful in patient education and counselling. However, few of the pharmacists sampled in this study made use of PIs during patient counselling.

The most and the least sought-after information in PIs by the pharmacy clients were dose and disposal of unused medicines, respectively. This is slightly different from the reports from Sudan and Saudi Arabia.<sup>[20,21]</sup> The most used information in PIs in Sudan was dose, and in Saudi Arabia, it was indications, while the least used information in both Sudan and Saudi Arabia was precaution and mechanism of action, respectively. These differences may be due to geographical and socio-cultural differences. Patients or pharmacy clients access the information in PIs for diverse reasons such as familiarity with the drug, to stimulate adherence, to check if the appropriate drug was given and to decide whether to take the drug or not.<sup>[20]</sup> The information contained in PIs may trigger fear or anxiety, be reassuring, have no effect, cause loss of confidence in using PIs, cause the stoppage of the drug and lead to a reduction in dose or cause non-adherence.<sup>[19,20]</sup> These highlight the need for being proactive on the part of pharmacists to provide adequate and prompt information for patients especially when drugs are dispensed to patients without PIs.<sup>[24]</sup>

Less than half of the pharmacy clients regularly found it difficult to understand the content of PIs because of the medical jargons while one-fifth found PIs unreadable due to font size, font type



and spacing. This is similar to the reason given by the Sudanese patients,<sup>[20]</sup> but 75% of the patients in Saudi Arabia agreed that the content of PIs was readable and understandable.<sup>[21]</sup> However, the patients in the two studies complained that the PIs were too lengthy. The difference might be due to the stage of development in different countries in improving the design of PIs to optimise the delivery of their contents. The contribution of end-users should be considered in the design and content of PIs.<sup>[25]</sup>

Most of the pharmacy clients relied on information from healthcare professionals more than the information in PIs. This is corroborated by a study where 59% of the patients were satisfied with the information provided by the pharmacists.<sup>[20]</sup> Information from PIs may be needed by patients because the recall ability of patients after visits to health practitioners is 20–50%.<sup>[26]</sup> This also is contingent on the amount of information provided<sup>[27]</sup> and usually, about 50% of the information remembered by patients is incorrect<sup>[28]</sup> hence the need for PIs. Also, some of the pharmacists considered the information in PIs more reliable. Since health care providers sometimes lack up-to-date timely information needed for daily practice, accessing needed information in PIs may come in handy. A study reported that 87% of the pharmacists were approached by patients for further clarification on the information provided in PIs while 85% of the pharmacists stated that they referred patients to relevant portions of PIs after counselling.<sup>[6]</sup> The pharmacists should, therefore, be conversant with many PI contents, though this may be a daunting task.

### Strength and limitations of the study

The strength of the study lies in the evaluation of how community and hospital pharmacists utilise the information in PIs during consultation and counselling, and how pharmacy clients make use of the information in PIs. There are some limitations to this study. Therefore, the results presented should be interpreted in the context of the limitations. This is a self-report of intention and not of observed behaviour; hence, there is the possibility of over-reporting or under-reporting. The study was carried out in a city; thus, it may not be generalisable to pharmacists and pharmacy clients in other cities and the country at large. Also, the non-inclusion of inpatients and outpatients might affect the level of PI utility.

### Conclusion

The utility of PIs by pharmacists and pharmacy clients is moderate. Although patients rely more on the information provided by health care professionals than the information in PIs, most pharmacists seldom use the content of PIs in counselling patients.

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### Conflict of Interest

The authors have no conflict of interest to disclose.

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