Usability of Medicine Package Inserts for Chronic Diseases: A Survey of the Pharmaceutical Market in Jos, Nigeria

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Authors' contributions

This work was carried out in collaboration between all authors. Author BNJ conceived the idea and topic, designed the study and wrote the protocol and the first draft of the manuscript. Author UOA collected the data and wrote an aspect of the work. Authors BMA and MNN managed the analyses of the study. Authors DMU and NSJ managed the literature searches. Author MLPD reviewed the method and edited manuscripts. All authors read and approved the final manuscript.

Article Information

Original Research Article

ABSTRACT

Background: The burden of illness is increasingly tending towards chronic diseases while medication adherence is often unsatisfactory. The patient information leaflet is one model that has the prospect to improve medication adherence. Improving the readability and content based validity of medication information has great educational potential to influence adherence to medicines.
Objectives: This study assessed the readability and content based validity of patient information leaflets. It compared the readability and the content based validity of foreign and indigenous based patient medicine inserts.
Methods: The study was conducted in two tertiary hospitals in Jos, Plateau State, Nigeria. The study was a cross-sectional design. Sixty six leaflets for chronic diseases were randomly selected.

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Results: The mean Flesch readability ease was 23.17, the Flesch-kincaid grade level was 13.7 and mean word count was 1219.89. The average font size and line spacing were 1.13 and 1.15 respectively. Only 3% of the leaflets had pictogram. All the leaflets had information on generic name of the drug and indication for use. Nigeria indigenous leaflets recorded an average Flesch readability ease of 18.39 compared to foreign leaflets which had 25.43 (*p*-value = 0.070). Flesch Kincaid grade level for indigenous and foreign leaflets were 14.46 and 13.30 respectively (*p*-value = 0.075). The Nigeria pharmaceutical leaflets had a mean font size of 1.12 while the foreign leaflets had 1.13. The line spacing for Nigeria leaflets was 1.11 compared to the foreign leaflets which recorded 1.17. The foreign pharmaceutical companies were more likely to indicate information on pregnancy/lactation (p-value = 0.002), paediatric/geriatric (p-value = 0-007), shelf-life (p-value = 0.033) and handling of machine while on medication (p-value = 0.038).
Conclusion: These findings exposed the inadequacy and failure of the Nigeria's drug policies to coordinate and ensure best practices in the pharmaceutical sector. Our findings demonstrated that the readability and content validity of the indigenous patient information leaflets were poor. However, the foreign leaflets compared statistically better in terms of content validity.

1. INTRODUCTION

Improving the usability of medicine labels and package inserts is an innovative approach that can be applied across adherence to all therapies [1]. The medicine information leaflet (MIL) otherwise referred to as patient package insert (PPI) is a printed material that contains information based on regulatory guidelines for the safe and effective use of a drug [2]. 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 [3,4,5]. Improving the readability and enhancing patients' cognitive appraisal with pictograms significantly predicts adherence; conversely, complex medicine leaflets negates adherence [4, 6]. A study in Israel, found a MIL reading rate of about 50%. These researchers however, revealed that an insignificant proportion of the patients who read the leaflets developed anxiety and were non-adherent. They further stated that reading prescription inserts was associated with higher educational attainment and long-term diseases [7]. In Australia, use of medicine information was associated with the following variables: patients' level of health literacy, health locus of control, occupation, patients coping mechanism and chronic diseases [8].

In the course of interaction between health care professionals and patients', essential aspects of the medication might be inadvertently omitted [9]; sometimes patients received suboptimal counselling about newly prescribed medications especially about the duration of medication use and potential adverse effects [9]; even after a good oral communication, a great deal of information might be misunderstood or forgotten, thus the provision of patients prescription leaflets is a great challenge [10]. Poorly informed patients are not likely to adhere to medication [6]; such patients may benefit from the patient package inserts. Education provides the needed information for behavioural change; however, this often requires motivation and behavioural skills which increase the likelihood for adherence; thus, for adherence to occur, the relationship between information and motivation construct must be strong [11]. In real terms, a highly motivated person may have inadequate information, or a highly informed person may have low motivation.

Tarn and Flocke [12] using an observational study found that independent of race and educational status, about two-thirds of patients were able to recall all the prescription information provided to them. Thus, incorporating medication information leaflets as additional educational material could improve information recall; broaden the knowledge and the capacity of the patient to participate in his/her care process and to make informed decision.

The advent of consumerism has brought about a fundamental development that is shaping the health service delivery especially in the developed world; patients are no longer passive recipients or subjects with unflinching and unquestionable compliance to medical maneuvering; instead, they are critical reflexive agents who would not accept at face value the

authority of science and medicine [13]. This brings to fore, the relevance of MIL as patients will also want to know the details about the medicine they have to contend with for possibly the rest of their life.

In some countries, the criteria and prototype template for the design of package inserts have been developed, however, strict implementation of legislative instruments for compliance with these guidelines has been quite challenging [2,14]. In Nigeria, the criteria, structure and legislative instruments regulating PPL is not quite elaborate and explicit; the emphasis is more on generic nomenclature, pharmaceutical content of the medicines and the adoption of English language as medium for written communication [15]. Collaboration between medicine regulatory agencies and the pharmaceutical manufacturing sectors in the development and adoption of a uniform guideline for package inserts will enhance the quality, clarity, safety and satisfaction of the consumers [16].

This study sought to assess the readability and content based validity of medicine information leaflets that are used in the pharmaceutical market in Jos, Nigeria. It compared the readability and content based validity between the Nigeria indigenous pharmaceutical leaflets and the foreign leaflets.

2. METHODS

2.1 Study Site

The study was conducted in Plateau State Specialist Hospital, Jos and Bingham University Teaching Hospital, Jos, Nigeria.

2.2 Study Design

The study was a cross-sectional survey of medicine information leaflets.

2.3 Ethical Consideration

The ethical clearance for this study was obtained from Bingham University Teaching Hospital, Jos and the Plateau state Specialist Hospital, Jos.

2.4 Sampling Method and Data Collection Instrument

Medicine information leaflets for specified chronic diseases were collected from two tertiary health centres in Jos. Medication information leaflets were collected from the out-patients department and the medical ward of these hospitals from 12th September to 13th November, 2015. The leaflets were sorted to avoid replication. However, medication information leaflet for a given drug was repeated if the drug was from different pharmaceutical company. Two hundred (200) leaflets were identified and shuffled. We selected a starting point that will divide 200 to give us a total number of leaflets less than 70 for feasibility. The 3rd of the leaflets was taken consecutively after shuffling and a total of 66 leaflets were collected. Our assessment showed that 24 of these leaflets (36.36%) were antihypertensive leaflets; 4 which represent 6.06% were leaflets for osteoarthritis; 6 (9.09%) were anti-diabetic leaflets; 16 (24.24%) represent anti-infective leaflets from antiretroviral clinic; anti-lipidaemic leaflets were 4 (6.06%) while anti-platelets leaflets accounted for 18.18%. We used a data collection proforma to abstracted relevant content-based information from the leaflets. Furthermore, we used venier caliper to measure the font size and line spacing between letters. Each leaflet was typed using MS Words Windows 7; proof reading was conducted and peer-reviewed. Reviewed leaflets were further transcribed into a software to assess the Flesch-Kincaid grade level scores (FGL), Flesch readability ease (FRE) and word counts of each leaflet.

2.5 Data Analysis

Statistical Package for the Social Sciences (SPSS) version 20 was used for analysis. Results were presented as descriptive statistics. Students T-test was employed to determine differences between mean scores while p-value < 0.05 was considered statistically significant.

3. RESULTS

This study assessed 66 medication information leaflets (MILs). The average Flesch readability ease was 23.17 and ranged from 0-58.7. Flesch-Kincaid Grade Level (FGL) has a mean score of 13.70, a standard deviation of 3.09 and ranged from 0-19. We found an average word count of 1,219.89 and a standard deviation of 1,110.23 with a range between 100-5483. About 65.2% of the leaflets were written in English only while 38.4% were written in both English and another language.

The mean font size and line spacing were 1.13 and 1.15 respectively with a standard deviation of 0.29 and 0.52 respectively. Only 3% of the leaflets have pictogram. All the leaflets have bold

headings (Table 1). Majority (74.20%) of the leaflets were written in black ink on a white paper. A total of 10.6% leaflets were presented in blue on a white paper. About 6.10% of the leaflets were written in blue and black ink on a white paper (Fig. 1).

3.1 Content-based Validity of Medication Information Leaflets for Chronic Diseases

All the leaflets indicated the generic name, indication for use and method of administration. Only 27.3% of the leaflets provided information on both how the drug should be handled and date when information about the medication was last updated. Generic names of additives and advice on handling of machine while taking the medicine were provided by 17(25.8%) and 5(7.6%) of leaflets respectively. The medication leaflets that gave information on both shelf life and reference were 9(13.6%). Only 7(10.6%) of the leaflets made provision for request for further information. None of the leaflets indicated information on the retail price of the medication (Table 2).

Table 1. Readability statistics for medication information leaflets used in chronic diseases

Readability variable	Mean ± Standard deviation	Range
Flesh readability	23.17	0 – 58.7
Flesh Kincaid reading ease	13.70±3.09	0 – 19
Passive sentences	26.74±13.35	0 – 60
Word counts	1219.89±1110.23	100 – 5483
Font size	1.13±0.29	
Line spacing	1.15±0.52	
Language	**Frequency (n)**	**Percentage (%)**
English	43	65.2
English and other	23	34.8
Pictogram		
Present	2	3.0
Absent	64	97.0
Bold heading		
Present	66	100
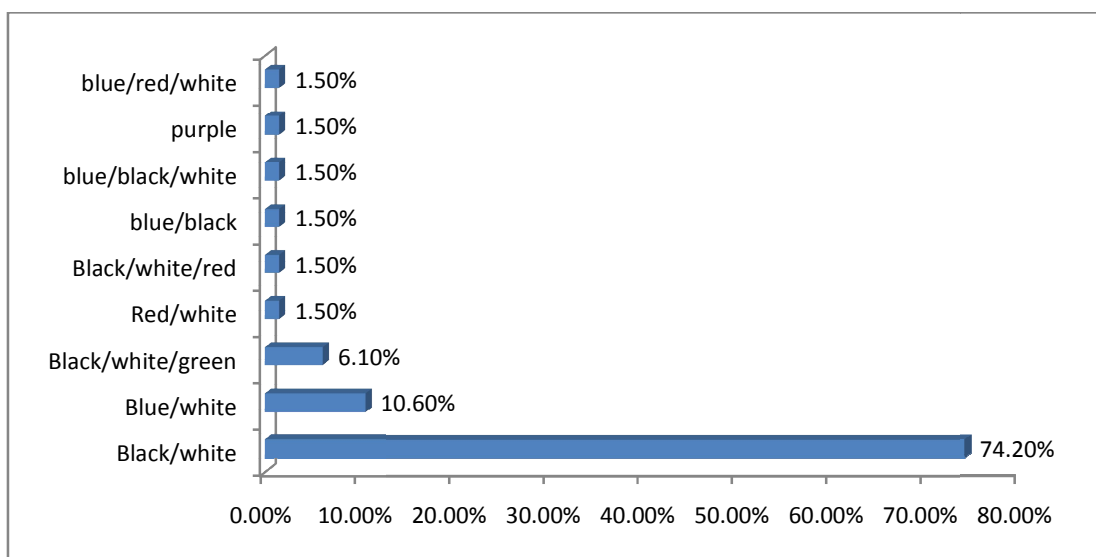
Fig. 1. Distribution of colour combination used on the information leaflets for chronic diseases

The average Flesch readability ease for indigenous companies was 18.39 with a standard error of mean of 2.85 while that of foreign companies was given as 25.43 (*p*-value = 0.070). The result obtained for Flesch-Kincaid grade level for indigenous companies was 14.56 with a standard error of mean of 0.45, while that of imported leaflets was 13.30 (*p*-value = 0.075).

Word count for indigenous and imported leaflet gave an average of 965.35 and 1341.10 respectively and a standard error of mean of 227.21 and 176.33 respectively (*p*- value =0.202). The indigenous companies have an average font size of 1.12 with a standard error of mean of 0.06, while that of imported companies had a value of 1.13 with a standard error of mean of 0.04 (*p*- value = 0.872).

Line spacing for indigenous leaflets gave an average of 1.11, while that of imported company was given as 1.17. About 70% of the indigenous leaflets were written in English only while 30% were written in both English and other languages. A total of 63% of the imported leaflets were written in English alone while 37% were written in both English and other languages. None of the indigenous leaflets have pictogram. Only 4.3% of the imported leaflets have pictogram (*p*- value = 0.344) (Table 3).

The study found that leaflets from foreign companies were more likely to indicate information on pregnancy/ lactation (*p*-value 0.000), paediatric/ geriatric (*p*-value = 0.002), handling of machine (*p*-value 0.038) and shelf-life (*p*-value = 0.033). The foreign companies provided information on special warning but this is not statistically significant (*p*-value = 0.148).

4. DISCUSSION

Flesch Readability Ease (FRE) measures textual difficulty which indicates how easy a text is to read. Studies by Raymol et al. [17] showed that FRE scale measures readability of 100 as (very easy to read), 65 (plain English), 30 (a little hard to read) and 0 (very hard to read). Flesch-Kincaid Grade Level (FGL) scores of 4.9 or lower (easily understood by 4th-grade student or lower), 5.0-5.9 (easily understood by an average 5th or 6th grade student), 6.0-6.9 (easily understood by average 7th or 8th grade student), 7.0-7.9 (easily understood by average 9th or 10th grade), 8.0-8.9 (easily understood by average 11th or 12th grade student), 9.0-9.9 (easily understood by average 13-15th grade student i.e. college student) and 10.0 and above (easily understood by an average college graduate).

Table 2. Content based validity of medication information leaflets for chronic diseases

Content variable	Present n (%)	Absent n (%)	Remark
Generic name	66 (100)	0 (0)	High
Indication	66 (100)	0 (0)	High
Method of administration	66 (100)	0 (0)	High
API	64 (97.0)	2 (3.0)	High
Dose	65 (98.5)	1 (1.5)	High
Storage information	63 (95.5)	3 (4.5)	High
Address of manufacturer	63 (95.5)	3 (4.5)	High
Side effects	62 (93.9)	4 (6.1)	High
Contra-indication	60 (90.9)	6 (9.1)	High
Drug interaction	41 (62.1)	25 (37.9)	Low
Overdose	36 (54.5)	30 (45.5)	Low
Pharmacokinetics	35 (53.0)	31 (47.0)	Low
Pregnancy/lactation	35 (53.0)	31 (47.0)	Low
Special warning	32 (48.5)	34 (51.1)	Low
Paediatric/geriatric	25 (37.9)	41 (62.1)	Low
Handling	18 (27.3)	48 (72.7)	Low
Information update date	18 (27.3)	48 (72.7)	Low
Generic others	17 (25.8)	49 (74.2)	Low
Shelf-life	9 (13.6)	57 (86.4)	Low
Reference	9 (13.6)	57 (86.4)	Low
Request for further information	7 (10.6)	59 (89.4)	Low
Handling of machines	5 (7.6)	61 (92.4)	Low
Retail Price	0 (0)	66 (100)	Low

Table 3. Readability assessment of foreign and indigenous leaflets

Readability variable	Nigeria M ± SEM	Foreign M ± SEM	P -value
Flesch readability ease	18.39±2.85	25.43±	0.070
Flesch- Kincaid grade level	14.56±0.45	13.30	0.075
Passive sentences	26.40±2.40	26.90±2.24	0.879
Word counts	965.35±227.21	1341.10±176.33	0.202
Font size	1.12±0.06	1.13±0.04	0.872
Line spacing	1.11±0.12	1.17±0.08	
Language			
English	14 (70.0)	29 (63.0)	0.586
English and others	6 (30.0)	17 (37.0)	
Pictogram			
Present	0 (0.0)	2 (4.3)	0.344
Absent	20 (100)	44 (95.7)	

Table 4. Content based validity between the Nigeria and foreign countries

Content variable	Present		P -value
	Nigeria N (%)	Foreign N (%)	
Drug interaction	10(50.0)	31(67.4)	0.181
Pharmacokinetics	9(45.0)	25(56.5)	0.389
Pregnancy/lactation	4(20.0)	31(67.4)	0.000*
Special warning	7(35.0)	25(54.3)	0.148
Paediatric/geriatric	2(10.0)	23(50.0)	0.002*
Handling	0(0.0)	5(10.9)	0.125
Information update date	1(5.0)	17(37.0	0.007*
Generic others	5(25.0)	12(26.1)	0.926
Shelf-life	0(0.0)	9(19.6)	0.033*
Request for further information	2(10.0)	5(10.9)	0.916
Handling of machines	2(10.0)	16(34.8)	0.038*

*P-value <0.05

This study calculated an average Flesch readability ease of 23.17. This implies that these medication leaflets can only be read and understood by college graduates. Based on readability level, these materials are categorized as very hard to read. A client who is not a college graduate will actually find it difficult comprehending these materials. The Flesch–Kincaid grade level gave a mean value of 13.17. This implies that these leaflets are easily understood by average college graduates. That is, a patient whose academic level is not up to college (university) will find it difficult understanding the information on these medication leaflets. The national population census conducted in 2005 in Nigeria revealed that only 10% of Nigerians acquired tertiary education. This implies that majority of patients will find these medication leaflets difficult to read. Studies have shown that FRE and FGL are inversely related. This means that a material with high FRE will always have a low FGL [17]. This is consistent with this study which had low FRE with a high FGL. Comparing the findings of this study with the result carried out in Slovenia by Karin et al. [18] revealed that both studies have similar findings.

Word count per sentence is important in readability study. A sentence with fewer words is easier to understand than sentence with many words. Findings in this study showed that the number of words per sentence is much. This made these patient information leaflet (PIL) difficult to understand. Number of word per sentence affects readability significantly.

Legibility measures both font size and line spacing. An average of 1.13mm and 1.15mm were obtained for font size and line spacing respectively in this study. These values are below the standard given by European Guideline [19], which gave a minimum of 1.4mm and 3.0mm for both font size and line spacing respectively. When the font size of PIL is too small, readability is adversely affected. The effect

is worse in this study which is based on chronic diseases that is more prevalent among the elderly. The font size and line spacing to a large extent either encourage or discourage the patient to read the leaflets. Studies by Carla et al. [20] discovered that PILs presented in font sizes and line spacing below the recommended standard are poorly read by patient. Majority of the leaflets were presented in English. This is acceptable since English is the official language in Nigeria. However, this study is considering medication leaflets used in chronic diseases. Chronic diseases are mostly associated with elderly people and majority of them only understand their local languages. PILs should be produced in the local languages as well. Jignesh et al. [21] revealed that availability of patient oriented insert, in an understandable language, will be a step forward for effective dissemination of healthcare service.

Most information is easier to understand with illustrations (pictogram). Illiterates find it easier to comprehend information given in form of illustrations than written ones. Carla et al. [20] conducted a cross-sectional descriptive study to assess the readability of medication information leaflets. Their findings revealed that pictogram was rarely included in leaflets. This finding is consistent with the finding of this study. Only 2 of the 66 PILs used in this study had pictogram in them. All the leaflets have their headings in bold letters. This helps in enhancing readability because it helps the patient to read the caption of the leaflet at a glance. Complementing pictogram with written information may increase the degree to which patients comprehend, recall and adhere to their treatment regimen [22]. Majority of the leaflets used in this study were printed in black and white. Printing the body of the text in white and black provides optimum colour contrast. Good leaflets should not have more than two colours on the same leaflet [23].

4.1 Content Based Validity

This study indicates that information relevant for safe and effective use of medication was not uniformly mentioned in the inserts analyzed. All the medication leaflets used in this study indicated the generic name of the drug. This implies that the companies are aware of the relevance of generic name to the patients. The importance of indicating generic name of a drug is mostly seen in cases where the brand product a patient has been on is out of stock and there is need for generic substitution. Most importantly,

this study considered PILs used in chronic diseases. By implication, the patient needs to take the medication for a long period. Therefore, the need for generic substitution is bound to arise at one point or the other.

Information about indication for all the leaflets was provided. This goes to say that the company saw the need for the patient to have this information. This information points out what the drug is really used for. For instance, a patient with co-morbidity can hardly escape polypharmacy. In this case, the patient can always read the PIL that comes with each drug and know what each drug is indicated for. Information pertaining to method of administration was indicated in all the leaflets. The importance of this information to patient is based on the fact that the efficacy of a drug depends on its method of administration among other factors. The right drug administered using the wrong method yields a less efficacious result.

The information about the active pharmaceutical ingredient (API) was indicated in about 97% of the medication leaflets used in this study. This percentage is encouraging but pharmaceutical companies needs to improve to 100%. This is because API accounts for the actual activity of the drug and the patient has the right to know what he/she is taking especially in chronic diseases were the patient is expected to take this drug for life. This study found that 1.5% of the leaflets did not provide information about the dose. This information is important especially in situation where the patient has memory challenges. Information about the dose of medication can also help the patient to take the proper dose at the right time. Information about storage condition of the drug and the address of the manufacturer was not indicated in 4.5% of the leaflets. It is important to indicate this information because the right drug when stored under the wrong condition adversely affects the efficacy and quality of the drug. In emergency cases, pharmacist or the clinician may need to contact the manufacturer or distributor directly. This goes to show the importance of the address of the manufacturer. For instance, situation where the stock level has reached the emergency order point, the clinician needs the contact of the manufacturer or distributor to place the emergency order. Since the PILs considered in this study are those used in chronic diseases, implying the patient needs to use them for a long period, the issue of out of stock can hardly be avoided.

About 4 (6.1%) and 6 (9.1%) of the leaflets used in this research omitted information on side effect and contra-indication respectively. Although, it is documented that information about side effect are likely to frighten and cause anxiety amongst patients [24]; it is imperative that the patient is subtly informed about these effects. A study from Southern India discovered that of a total of 2340 hospital admission , 6.4% were drug related of which 50% were due to side effect, with majority being reported as preventable [25]. It could be useful to follow the recommendation of FDA to highlight important information with the purpose of drawing the attention of the prescriber to it.

This study found that 25 (37.9%) of the leaflet did not indicate information on drug interaction, 30 (45.5%) excluded information on over-dose while 31 (47.0%) did not state the pharmacokinetics of the medicines. Providing information on drug interaction is very beneficial to the patient. For instance, a patient with co-morbidity should have information about how medication for one ailment affects medication of the other. This helps in spacing the drugs so as to avoid drug interaction. The importance of information about overdose can never be over emphasized. When it comes to life, there is nothing like excess information. A prescriber may not be able to fully inform patient on what to do in case of overdose but by reading the PIL the patient can abstract this information and take precaution especially in emergency cases. The knowledge of pharmacokinetic of the drug will also help the prescriber titrate the dose of the drug based on individual patient's need. This helps avoid accumulation which can lead to toxicity.

Findings from this research also revealed that information on pregnancy/ lactation and paediatric/ geriatric were not indicated in 47% and 62.1% of the medication leaflets respectively. Normally, pregnant/ lactating women and paediatric/ geriatric patient are considered as special population when it comes to drug. Therefore, it is imperative that each medication leaflet contains information on the safety of the use of the drug in these groups of people.

Only 13.6% of the medication information leaflets used in this study provided information on handling of machine while on the medication. Pharmaceutical companies are encouraged to indicate this crucial information on the medication leaflets especially in cases where the medication can cause drowsiness. Indication of information about shelf-life was present only on 13.6% of the medication leaflets. Information on Shelf-life is important as drug that has exceeded its shelf-life may still be safe for consumption but quality is not guaranteed. This can lead to poor control of diseases like hypertension and diabetes [2]. Information on retail price of the drug and reference were not provided by 100% and 57% of the leaflets. Patient should be well informed about the retail price and should be able to confer to references when required.

Findings of this study suggested that the medication inserts should be tested by group of experts prior to drug approval. This will ensure avoidance of lack of information and will guide towards an informed and better treatment outcome.

4.2 Comparative Assessment of Foreign and Indigenous Medication Information Leaflets

Findings from this study showed that majority of the indigenous leaflet are poorly prepared in terms of readability and validity of content. Raymol et al. [17] suggested that FRE scores of 30 to 0 was considered a little hard or hard to read while FGL scores of 100 was described as easily understood by college graduate.

Although, both the foreign and local pharmaceutical companies presented leaflets that were difficult to read; the foreign literatures were relatively easier to read. This difference is not statistically significant (*p*-value = 0.070). FGL for both foreign and indigenous leaflets gave a mean of 13.3 and 14.56 respectively (*p*- value = 0.075). The FGL grade the readability of both countries as 10 or higher (easily understood by average college graduate). Comparison of word count showed that foreign countries have more words (*p*- value = 0.202). Studies have shown that medication information leaflets with simpler and fewer words per sentence are easier to comprehend [17]. The font sizes of imported and indigenous leaflets are 1.13 and 1.12 mm respectively, while the line spacing was given as 1.17 and 1.11 mm respectively. Studies by European Guideline [19] gave a standard of minimum of 1.4 mm and 3.0 mm for both font size and line spacing respectively. Both companies failed to reach the standard value. By implication, the font size and line spacing were found to be quite small in this study. The smaller the font size, the more difficult it is for patient to read. Research has shown that maintaining the

standard font size and keeping the line spacing even aids readability [23].

Both the indigenous and foreign countries presented their PILs in both English and other languages. However, based on this study, foreign companies considered their local language more compared to Nigeria. This implies that the foreign companies took into consideration the fact that not everybody understands English especially the elderly who are more associated with chronic illness. An important issue for proper information dissemination to patients is making the information available in the language the patient best understands. For countries like Nigeria and India where level of literacy is low, language issue becomes very important. Studies have shown that there is need for medication inserts to be written in official and indigenous languages which the users are expected to understand [21]. Indigenous companies are encouraged to present their PILs in both English and indigenous languages since the PILs are targeted to both the literate and illiterate patients. Studies have shown that presenting information with illustration (pictogram) aids understanding [22]. Most people with low level of literacy can understand illustration easily. Manufacturers are encouraged to present the leaflets with an illustration for better understanding. Comparative assessment of the leaflets showed that both foreign and indigenous companies seldom include pictogram in their leaflets.

Findings of this study discovered that foreign companies tend to indicate information on pregnancy/lactation (*p*-value = 0.000), paediatric/geriatric (*p*- value 0.002) and shelf-life (*p*-value = 0.033) more. The difference between both companies is statistically significant. Information on drug interaction was indicated by 50% of indigenous leaflets while that of imported leaflets was 67.4% (*p*-value = 0.181). This difference was not statistically significantly. This study also revealed that foreign companies provided information on handling of machines 16(34.8%) more than Nigerian companies 10.9%, (*p*-value = 0.038). This is statistically significant meaning that the difference did not occur by chance i.e. there is actually a factor that can be said to be responsible for the difference. A similar study by Shivkar et al. [25] discovered that foreign medication information leaflets have better readability and content based validity which is in line with the findings of this study.

5. CONCLUSION

This study revealed that patient information leaflets used in chronic diseases have both poor readability and content based validity. This study provides the evidence for a thorough review of Nigeria's document on pharmaceutical leaflet in order to safe guard and promotes the health of the general public.

CONSENT

It is not applicable.

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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