

## ASSESSMENT OF THE QUALITY OF SELECTED ANTIBIOTIC PATIENT INFORMATION LEAFLETS WRITTEN BY NIGERIAN PHARMACEUTICAL COMPANIES

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DOI: njcpt.com.ng/101.1.2.8

### Abstract

**Background:** Patient Information Leaflets (PILs) help drug manufacturers disseminate essential information to the public. Every patient deserves the right to adequate information about any drug to be administered to them for any condition. Unfortunately, antibiotics are commonly misused and are largely available without prescription in Nigeria. Therefore, all patient education methods should be maximised to prevent antimicrobial resistance caused by indiscriminate use due to ignorance.

**Objective:** To assess the quality of antibiotic Patient Information Leaflets written by Nigerian companies in selected cities.

**Methods:** The antibiotics, tetracycline and ciprofloxacin were chosen for this study because of their frequent consumption and misuse among the Nigerian populace. Local brands of these drugs were obtained from 5 different states in Nigeria, and their quality was assessed using the National Agency for Food and Drug Administration and Control (NAFDAC) and Medicines and Healthcare products Regulatory Agency (MHRA) guideline as criteria.

**Results:** Most PILs were written in one language (English). Diagrams and pictorial illustrations were not commonly used in PILs assessed. Ciprofloxacin brands had a mean leaflet score of 83 %, and tetracycline brands had 76.5 %. In statistical comparison, both drugs had no significant average difference ( $p>0.05$ ). However, tetracycline brands had lower quality as they had a less satisfactory mean score.

**Conclusion:** The PILs performed satisfactorily but require improvement, as health education promoting materials should always contain sufficient information to optimise pharmaceutical care.

**Keywords:** Antibiotics, Patient Information Leaflets, Quality Assessment, Compliance

### Introduction

Accurate and adequate drug information plays a vital role in the rational use of drugs, the lack of which may result in several consequences, including drug therapy failure, preventable adverse effects, development of drug resistance, hospitalisation, and death, thus defeating the goal of pharmaceutical care[1,2]. Furthermore, the advent of the information age has changed the passiveness of patients towards medical care as they become more active in the decision-making process on their health and seek more information on their healthcare needs[3]. Consequently, patients' empowerment via access to quality, up-to-date drug and health information becomes pertinent to make decisions on their health[4]. Furthermore, patients with chronic conditions such as hypertension, diabetes, stroke, and asthma need to have sufficient information about their condition because care is long-term[5]. Drug labels, including the package leaflet and drug advertisements, have been reported as a source through which healthcare professionals, patients, caregivers and members of the public get drug information to make healthcare decisions[6]. However, verbal relay of important drug information to the patient is often inadequate because of limited interaction between patient and health care providers due to large patient load and low retention of information by patients[7].

Patient information leaflet (PIL), also referred to as drug information leaflet (DIL), is a printed material that contains information for the safe and effective use of drugs for the patient, caregivers, and health care professionals[1,7]. It is written by a pharmaceutical company in line with specific regulatory guidelines and serves as a guide to health care professionals in patient counselling and education, allowing coverage of important details[8,9]. A written information leaflet thus serves as a valuable reference tool for patients promoting the safe and effective use of medicines. In addition, PIL has been recognised as an essential strategy to improve patient medication adherence[10]. For example, Gotsch and Liguori[11] reported that the inclusion of PILs in antibiotic regimens improved compliance. While this does not override the importance of verbal counsel, the PIL must be structured in a way that allows the patient to maximise the information contained therein[12].

The elements of information contribute significantly to its compelling power. Hence, typography, font size, line spacing, bullet points, and headers in PILs have recommended specifications. For example, the European Commission[12] recommends the most legible fonts (e.g. times new roman) and minimum font size of 9 for PILs for the material to be legible at a glance. Headers and their appearance in simple forms (uniform headings) are also recommended to emphasise the necessary information and create a lasting impression on the reader.

The value of PILs to patients is reduced if they fail to educate them; hence, PILs must be accurate, up-to-date, clear, and comprehensive[13]. There is a need for pharmaceutical companies to design PILs in line with evidence-based guidelines and international standards with content that meets the needs of the targeted population[14]. PILs must comply with the appropriate national medicine regulatory agency guideline, which in Nigeria is provided by the National Agency for Food and Drug Administration and Control (NAFDAC)[15,16]. NAFDAC has provided a template for designing package inserts and mandates that information conforms with the Summary of Product Characteristics (SmPCs). This template is in line with the recommendations of the European Union[17] and is required to follow a particular order and should provide the name of the medicinal product with its strength and dosage form, indication, contraindication, possible adverse reactions, amongst others[15,18]. Furthermore, NAFDAC mandates that information on labels should be accurate, written primarily in the English language with font size and style type that allows for legibility and clarity.

Antibiotics have been misused and overused by the Nigerian public due to over-prescription by health workers and easy accessibility. Nevertheless, the majority of the Nigerian public is inclined towards antibiotics at the slightest opportunity due to their belief that it could take care of most of their ailments. Irrational antibiotic use is, therefore, a concern[19].

Due to the few studies in this area, further research is needed to add to the existing body of knowledge. This study evaluates the quality of antibiotic PILs written by Nigerian indigenous pharmaceutical companies using standard guidelines. Therefore, this research focuses on the assessment of locally published medication leaflets found readily in drug stores. The components of the leaflets were assessed in comparison with standard criteria.

## **Methods**

### **Data collection**

A cross-sectional, observational, descriptive study was conducted using patient information leaflets (PILs) collected from medicines packaged in Nigeria. The leaflets were obtained from privately-owned community pharmacies in Lagos (2 urban locations), Cross-river (3 urban locations), Rivers (2 suburban and one urban location), Akwa Ibom (4 urban locations), and Abuja (5 urban locations) with assistance from the pharmacists working in these settings. A large pool of leaflets was collected for ciprofloxacin and tetracycline. The sample consisted of 25 ciprofloxacin PILs and 10 PILs of tetracycline.

### **Sampling**

The leaflets were obtained using convenience sampling from all accessible community pharmacies in the study locations.

### **Assessment**

An assessment tool and scoring system were developed by creating checklists and using the National Agency for Food and Drug Administration and Control (NAFDAC) and Medicines and Healthcare products Regulatory Agency (MHRA) criteria[14,17,20]. The developed tools were used as a reference, and the researcher checked the availability of information in the PILs against the developed tool while assigning scores. The information on the tool was developed into two categories: readability and presentation (which contains the font size, colour contrast, line spacing, headers and bullet points) with a total of 5 points, then clinical information (such as the drug name, strength, composition, contraindications, precautions, side effects, interactions among others) to a total of 15 points. The overall achievable score was 20 points (readability/presentation + clinical information). A maximum of 1 Point was given where the criterion was met. Each leaflet score was presented as a percentage, and each leaflet was rated based on its percentage score.

### Statistical analysis

After data collection, the data were analysed using Statistical Package for the Social Sciences (SPSS) version 23. Descriptive statistics and student's t-test were used for data analysis. A p-value of < 0.05 was considered statistically significant.

### Result

Ten brands of tetracycline were used for the study. Pictograms were not used in any of the information leaflets. Consultation with patient groups during leaflet development was not indicated. Eighty per cent of the leaflets were written in English, and others were written in English and French. Eighty per cent of the tetracycline brands leaflets gave information concerning the use in pregnancy, contraindications, and warnings. Total leaflet scores for the individual tetracycline brands leaflets were 60 %, 70 %, 75 %, 80 %, 85 %, and 90 %. Thus, indicating that all leaflets assessed passed the tests ranging above-average. The mean leaflet score was 76.5 %. Tables 1 and 2 show the results from the tetracycline leaflet analysis.

**Table 1: Readability and presentability test for tetracycline**

Readability and presentability test	Tetracycline brands that met the criteria
The font size of information (must be $\geq 8$ )	80 %
Colour contrast between text and background	100 %
Use of headers (Headers and sub-headers should be present)	70 %
Line spacing (there should be at least a line spacing to separate the sub-headings)	90 %
Use of bullet points or semi-colon for each side effect, warning, precaution, and contraindication (They must be broken up into segments)	90 %
Text in simple English	70 %
Adequate information	70 %
Dosage information	90 %
Precaution information	70 %
The leaflet is written in more than one language	20 %

**Table II: Tetracycline leaflet content**

Leaflet content	Percentage of PIL containing this information
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Drug name	100 %
Drug composition	100 %
Drug strength	100 %
Therapeutic indications	100 %
Side effects	100 %
Address of manufacturer	100 %
Drug class	10 %
Drug description/pharmacology	10 %
Side effects	10 %
Contraindications	10 %
Precautions	30 %
Drug interaction	30 %
Dosage	10 %
Storage condition	10 %
Pack size	40 %
Adequate information	70 %
"Keep all medicines away from children."	20 %

The total number of ciprofloxacin brands used to carry out this study was 25. Three ciprofloxacin brands used a chart to elaborate their points while (22 brands) did not. In assessing the leaflet content of all 25 brands, all brands had the drug name, drug composition, drug strength (in mg), and therapeutic indication listed. The language used in the leaflets was written was also assessed. Twelve per cent of the brands were written in more than one language, and only two languages were used (English and French). Twenty per cent of the brands stated in the leaflet the patient group involved in its development. Seventy-six per cent of the brands gave pregnancy consideration under contraindications and precautions. The mean leaflet score of the ciprofloxacin brands was 83 %. Tables 3 and 4 show the results from ciprofloxacin leaflet analysis.

**Table 3: Readability and presentability test for ciprofloxacin**

Readability and presentability test	Ciprofloxacin brands that met the criteria
The font size of information (must be $\geq 8$ )	80 % (20)
Colour contrast between text and background	100 % (25)

Use of headers (Headers and sub-headers should be present)	84 % (21)
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**Table 4: Ciprofloxacin leaflet content**

Leaflet content	Percentage present
Drug name	100 %
Drug composition	100 %
Drug strength	100 %
Therapeutic indications	100 %
Side effects	84 %
Address of manufacturer	96 %
Drug class	96 %
Drug description/pharmacology	96 %
Contraindications	88 %
Precautions	80 %
Drug interaction	84 %
Dosage	96 %
Storage condition	88 %
Pack size	88 %
Adequate information	64 %
"Keep all medicines away from children."	80 %

## Discussion

The current study found that a good percentage of the samples passed the assessment on readability and presentation. However, in their recommendations, the European Commission<sup>[21]</sup> buttressed the importance of adequate line spacing as a tool for making the text more lucid and comelier to the reader's eyes. Although all samples had good contrast between the text and the background, making the text easy to read without straining the eyes, a few ciprofloxacin brands had unsatisfactory line spacing.

The present study observed that the majority of the PILs were written in English. A few leaflets were written in both English and French language. Although there is no specific requirement for the choice of languages to include in this kind of document, it is suggested that including one or more of the major indigenous languages can have

more impact in passing drug information and encourage reading<sup>[22]</sup>. A significant number of tetracycline brands had an unsatisfactory level of English grammar. This means that a high percentage of patients may likely find it challenging to comprehend the leaflet information.

Herber et al.<sup>[23]</sup>, in their research, observed that some patients displayed a lot of negative reactions (such as discontinuation, phobia for medication leaflets, confusion, anxiety) arising from misinterpretation, especially from outlined side effects and lack of comprehension of "big words". It is recommended that short and straightforward sentences be used in PILs<sup>[24]</sup>. Owusu et al.<sup>[25]</sup> also noted that the message perceived from PILs is one of the reasons some patients abandon their medication. Hence, it must be easy to read.

According to Owusu et al.<sup>[25]</sup>, the appearance of a medicine leaflet was observed to influence the decision of participants to go through the information contained in them. Therefore, the presentation is as important as the message to be passed. An unappealing leaflet would not likely be read in the first place, thereby defeating its purpose. A few PIL samples buttressed their information further with pictorial representation, which can be more appealing than other leaflets. It is believed that diagrams and pictures aid comprehension in cases where the text may be ambiguous. Also, some people tend to understand faster and be more willing to go through the leaflet when visualisation is aided<sup>[22]</sup>. It was even recorded to improve compliance to medication in a study carried out by Shareef et al.<sup>[24]</sup>.

The content and arrangement of information in a medicine leaflet should have a smooth flow from drug name and properties to its effect and other information. The NAFDAC guidelines for drug PILs give good illustrations of content arrangement. Content-wise, both brands performed satisfactorily, with ciprofloxacin PILs performing better than those of tetracycline.

MHRA<sup>[26]</sup> requires that the drug's brand name and generic name be displayed conspicuously for proper identification, alongside the use specification (paediatric or adult). All sampled leaflets fulfilled the criterion of displaying these names.

The dosage form, drug description, therapeutic indication, and pack size were also outlined by MHRA<sup>[26]</sup> in the PIL arrangement requirements, stated imperatively to be written in English. The sampled PILs fulfilled all criteria except for 40 % of tetracycline brands which did not have pack size included in their leaflets. Although highlighted in the MHRA document, it may be possible that this is not a stringent requirement. However, this information is needed for the sake of clarity and documentation.

Essential information like drug composition is vital. Active constituents or excipients may elicit adverse reactions in a patient due to individual factors such as allergy and genetics or other factors such as drug interactions and co-morbidity. This information will prevent an adverse event when the ingredients can be easily spotted on the leaflet<sup>[7]</sup>. Therefore, all sampled leaflets contained drug composition information.

The inclusion of side effects of a drug is highly essential to properly educate the user on what to expect. All leaflets fulfilled this requirement. Additional information about safety such as storage conditions, keeping medicines out of reach of children and precautions are essential as they prevent drug misuse and mishandling<sup>[7]</sup>. Most of the sample leaflets included this information and hence, can promote informed rational drug use.

The majority of the PILs did not include the patient group involved in the development of the drug. Although this was not an outright requirement in the published guidelines, including this detail would increase the trust and confidence of readers.

Both drugs did not have a significant difference in performance. However, the quality of information obtained from leaflets affects the comprehension of patients and, consequently, their level of trust in the drug<sup>[27]</sup>. This guides the decision of the patient and hence should be critically reviewed before approval of leaflet content.

In general, the evaluation of PILs gives an idea of their potential impact and is essential as a means of reference during recommendation. Adepu and Sammy<sup>[28]</sup> highlighted the importance of leaflets as having a significant impact on patient education when included as a means of information dissemination. As much as health professionals encourage people to be more conscious about their health, it should be iterated that highly comprehensive and adequately informative materials be made available.

## Conclusion

The study findings suggest that the quality of PILs in Nigerian-packaged medicines are slightly above average. However, this indicates that there is much room for improvement. This could be made better if regulatory agencies enforce requirements for PILs.

## Acknowledgement

The authors are grateful to the Young African Researchers' Academy for facilitating the research.

## Conflict of interest

The authors declare no conflict of interest.

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