

READABILITY OF DRUGS AND CHEMICALS PACKAGE INSERTS INFORMATION: A SURVEY OF THE NIGERIAN MARKET

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Article Received on 06/03/2018

Article Revised on 27/03/2018

Article Accepted on 17/04/2018

ABSTRACT

Background: Readability of package inserts (PIs) of drugs, chemicals, reagents, vaccines and similar products is yet to receive adequate attention as little or no concern is accorded to font sizes of leaflet designs especially in the developing nations. Print is the medium for visual reading. Print size has been of interest to typographers and to vision researchers. Simplicity in information dissemination in global health delivery services should not be compromised as problems associated with poor designs of PIs resulting in high rate of misinformation of patients and users of agrochemical products need urgent intervention. **Methods:** The study examined a total of 1,769 PIs of pharmaceutical and chemical products in Nigeria. These were collected during the months of October 2016 through January 2018 and font size determined by comparison with the Jaeger eye chart. **Results:** The distribution of various drugs according to class and chemicals/reagents and vaccine leaflets depicts the general population of the sample with 1443 and 326 respectively, while PIs were printed in font size between N.5. and N.24. PI's N.5. – N.8. was significantly more (63.41%); (62.42%) than N.10. – N.12. (34.37%); (27.61%). F-ratio equals 8.81544; 2.04748 (P-values 0.05), thus a statistically significant difference between the means of the 8 variables at 95.0% confidence level. **Conclusions:** The package inserts studied do not meet up with readability standard, thus, there exists an infringement on the right of consumers to receive information. A general font size of at least 10-12 to range is suggested for NAFDAC's adoption.

KEYWORDS: Package Inserts, Drugs, Chemicals, Compliance, Font size, Readability, Nigeria.

1.0 INTRODUCTION

Simplicity in information dissemination in global health delivery services should not be compromised. Problems associated with poor designs of leaflets of drugs, chemicals, reagents, vaccines and other similar products need urgent intervention. Trivial attention is accorded to font sizes of leaflet designs especially in the developing nations.^[1] Despite the consistent criticism of the issues surrounding readability of inserts/leaflets of drug and

chemical products,^[1,2,3] the major problem associated with such is small writing.^[4]

National Agency for Food and Drug (NAFDAC) did not really emphasize on the readability of inserts in the guidelines for registration of drugs and related products manufacturing in Nigeria, as paragraph D (1) only states that "Labeling shall be informative, clear and accurate" NAFDAC.^[5] However, article 59 (3) of the amended European Union's (EU) medicine law, Directive

2001/83/EC, demands that medicine package inserts are legible, clear and easy to use and that readability test results should reflect this.^[6] Also the new EU readability guideline draft, revised September 2006, recommends applying a general font size for optimization, of at least 12 pt.^[7]

As regards labeling and packaging including standardization of font, size, colour and information, labels of ampoules, avoidance of similar packaging and presentation of drugs are specific-evident recommendations for the minimization of errors in intravenous drug administration.^[8] The readability of the package leaflets is an essential issue for the safety and rational use of medicines after they are prescribed or dispensed in pharmacies. Patients may independently consult the package leaflets to clarify their doubts, such as information on medicine administration.^[9,10,12] Some researchers assert that 10 and 11 pt are optimal font sizes for package inserts, as these sizes are more legible.^[13,14] Palpable emphasis on font sizes/letters language, legibility, clarity, colour and patients education level has to be considered compliant with recommendations of Food and drug association of country, region and general world standards.^[15,16,19] The inclusion of package leaflets inside all medicine packages is obligatory in the European Union. In accordance with regulations, the package leaflets must be organized in pre-defined sections and written in a clear and comprehensible way.^[20] Focus of labels should be on legibility, ease of identification and avoidance of look-alike labels, rather than information for quality control of medication manufacture and distribution especially for suitable labeling of small containers.^[21] The term “labeling” designates all labels and other written, printed, or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term “label” designates that part of the labeling upon the

immediate container.^[22] The size and shape of printed symbols determine the legibility of text and properties of human visual processing play a dominant role in constraining the distribution of print sizes in common use.^[23] The legibility of print depends on physical characteristics of text and also on task demands, viewing conditions, and the vision status of the reader. Several physiological and behavioral methods have been used for measuring legibility.^[24] Recent theoretical developments on crowding indicate that character spacing, which usually co-varies with print size, may be the operative variable.^[25] Vision researchers care about size because the underlying mechanisms for encoding pattern-spatial-frequency channels or their neural counterparts the receptive fields-vary in size. Clinical vision researchers care about print size in the determination of visual acuity and in refractive correction (using the ubiquitous letter charts), and in the prescription of magnifiers for people with low vision.^[23] This study investigated the compliance of retailed pharmaceutical, chemical and reagent products with standards and regulations especially relating to font size and readability of package inserts (PIs) in Jos, Plateau State, Nigeria.

2.0 METHODS

A total of 1,769 package inserts of pharmaceutical and chemical products available in Nigeria were collected during the months of October 2016 through January 2018 in Jos, Plateau State, Nigeria. Collected PIs were grouped into two – Drugs which were further divided into various drug classes and Chemical/Reagents/vaccines products. The font sizes of samples were observed and determined by comparison with standard font sizes using the Jaeger eye chart. The statgraphics (Version 26.5) package was used for the statistical analysis using the multiple-sample range comparison.

3.0 RESULTS AND DISCUSSION

Table 1: Distribution of drugs with corresponding font size on Jaeger chart.

| Drug Classification | Font size on Jaeger chart | | | | | | | | TOTAL |
|---------------------|---------------------------|------|------|-------|-------|-------|-------|-------|------------|
| | N.5. | N.6. | N.8. | N.10. | N.12. | N.14. | N.18. | N.24. | |
| Antimalarials | 27 | 12 | 67 | 21 | 15 | 1 | 0 | 0 | 143 |
| Antimicrobials | 41 | 20 | 24 | 61 | 22 | 0 | 0 | 0 | 168 |
| Antianaemics | 22 | 21 | 12 | 9 | 4 | 0 | 0 | 0 | 68 |
| Analgesics | 44 | 21 | 44 | 12 | 11 | 0 | 0 | 0 | 132 |
| Antipsychotics | 5 | 5 | 14 | 4 | 12 | 0 | 0 | 0 | 40 |
| Antidepressants | 3 | 1 | 18 | 11 | 6 | 0 | 0 | 0 | 39 |
| Antihypertensives | 3 | 7 | 17 | 17 | 11 | 0 | 0 | 0 | 55 |
| Antidiarrhoeal | 2 | 1 | 5 | 3 | 3 | 0 | 0 | 0 | 14 |
| Anti-helminthics | 3 | 1 | 4 | 1 | 1 | 0 | 0 | 0 | 10 |
| Anti-emetics | 2 | 1 | 4 | 0 | 2 | 0 | 0 | 0 | 9 |
| Anxiolytics | 0 | 2 | 5 | 2 | 0 | 0 | 0 | 0 | 9 |
| Anticonvulsants | 0 | 0 | 2 | 5 | 1 | 0 | 0 | 0 | 8 |
| Anticoagulants | 1 | 1 | 3 | 2 | 2 | 0 | 0 | 0 | 9 |
| Antacids | 6 | 4 | 9 | 3 | 11 | 0 | 0 | 0 | 33 |

| | | | | | | | | | |
|----------------------|------------|------------|------------|------------|------------|-----------|-----------|----------|-------------|
| Antihistamines | 3 | 3 | 5 | 1 | 22 | 0 | 0 | 0 | 34 |
| Anti-asthmatics | 2 | 5 | 18 | 7 | 2 | 0 | 0 | 0 | 34 |
| Anti-snake venom | 2 | 2 | 4 | 0 | 3 | 0 | 0 | 0 | 11 |
| Anaesthetics | 4 | 1 | 13 | 2 | 5 | 0 | 0 | 0 | 25 |
| Corticosteroids | 2 | 0 | 14 | 2 | 6 | 0 | 0 | 0 | 24 |
| Muscle relaxants | 16 | 10 | 3 | 23 | 13 | 0 | 0 | 0 | 65 |
| Mydriatics | 34 | 27 | 14 | 12 | 12 | 0 | 0 | 0 | 99 |
| Infusions | 4 | 2 | 5 | 2 | 3 | 0 | 0 | 0 | 16 |
| Laxatives | 12 | 21 | 21 | 13 | 10 | 0 | 0 | 0 | 77 |
| Oxytocic agents | 3 | 6 | 10 | 5 | 7 | 0 | 0 | 0 | 31 |
| Vitamins | 20 | 47 | 42 | 47 | 16 | 0 | 0 | 0 | 172 |
| Miscellaneous agents | 11 | 14 | 31 | 14 | 17 | 17 | 14 | 0 | 118 |
| TOTAL | 272 | 235 | 408 | 279 | 217 | 18 | 14 | 0 | 1443 |

Table 2: Distribution of Chemicals/Reagents/Vaccines Products with corresponding font size on Jaeger chart.

| Font size on Jaeger chart | | | | | | | | | |
|---------------------------|-----------|-----------|-----------|-----------|-----------|-----------|----------|----------|------------|
| Test Types | N.5. | N.6. | N.8. | N.10. | N.12. | N.14. | N.18. | N.24. | TOTAL |
| Vaccines (e.g Hep. B) | 2 | 5 | 3 | 0 | 1 | 0 | 0 | 0 | 11 |
| Culture Media | 5 | 1 | 5 | 0 | 1 | 0 | 0 | 0 | 12 |
| Stains | 5 | 7 | 7 | 3 | 0 | 0 | 0 | 0 | 22 |
| Chemicals | 37 | 45 | 10 | 19 | 22 | 14 | 2 | 0 | 149 |
| Reagents | 31 | 39 | 12 | 14 | 30 | 5 | 0 | 1 | 132 |
| TOTAL | 80 | 97 | 37 | 36 | 54 | 19 | 2 | 1 | 326 |

Figure 1: Chart of distribution of drugs with corresponding font size on Jaeger chart.

Figure 2: Chart of distribution of chemicals/reagents/vaccines with corresponding font size on Jaeger chart font size on Jaeger chart.

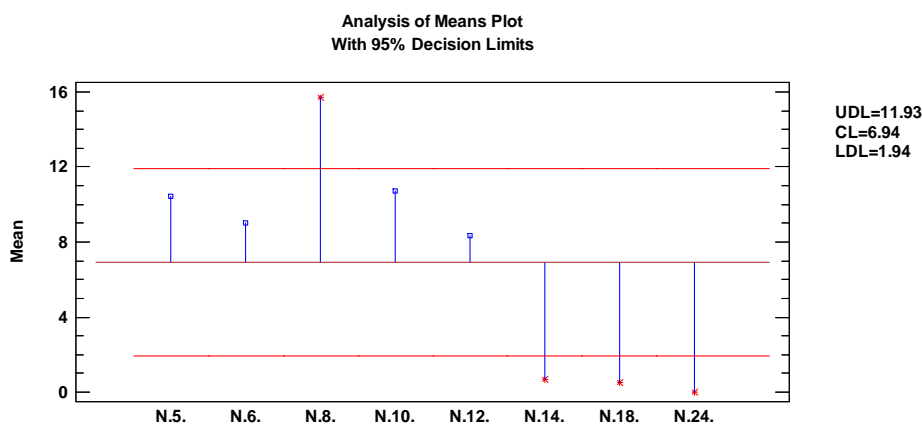


Figure 1: Means plot for drugs.

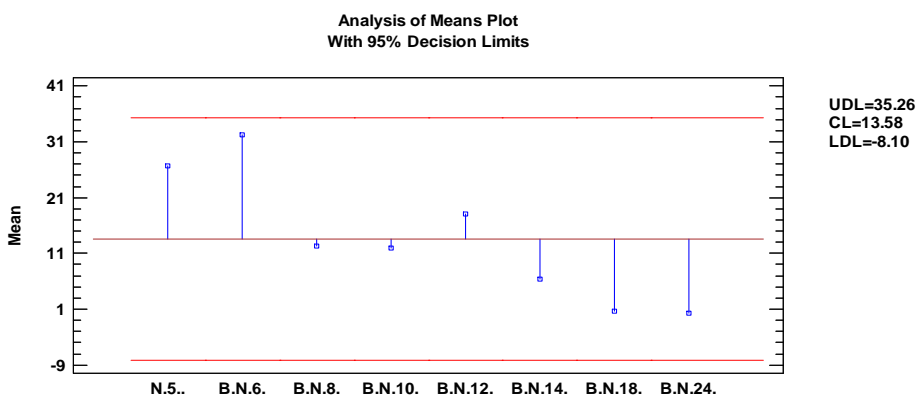


Figure 2: Means plot for chemicals/reagents/vaccines.

The distribution of various drugs according to class and chemicals/reagents and vaccine leaflets depicts the general population of the sample with 1443 and 326 respectively. Package inserts corresponding to the font sizes on the Jaeger eye chart were N.5 (272; 80), N.6. (235; 97), N.8. (408; 37), N.10. (279; 36), N.12. (217; 54), N.14. (18; 19), N.18. (14; 2) and N.24. (0; 1) for drugs and chemicals/reagents and vaccines respectively (Tables 1 and 2) Another point to note in this study is that the PIs were printed in font size between N.5. and N.24. PIs N.5. – N.8. were significantly more (63.41%); (62.42%) than N.10. – N.12. (34.37%); (27.61%) for drugs and chemicals with P-value < 0.05 respectively. Furthermore, this implies that most of the drug/chemical package inserts in the Nigerian market are not within the readability range and this in itself is a big problem to the visual health and may lead to impaired information among Nigerian populace. The foregoing is deduced from the assertions by Boyce *et al.*, 1981 and Bernardini *et al* 2001 that 10 and 11 pt optimal font sizes for package inserts are more legible and that small writing in particular, is a cause of major problems.^[13,14] Moreover, according to our study, the F-ratio, for drugs equals 8.81544 while that of chemicals/reagents/vaccines equals 2.04748 both with P-value < 0.05, thus a statistically significant difference between the means of the 8 variables i.e. points N.5., N.6., N.8., N.10., N.12., N.14., N.18. and N.24. at 95.0% confidence level.

This study showed that most of the PIs of drugs and chemicals/reagents/vaccines in Nigerian market are of fonts N.8. (Fig.1), and N.6. (Fig.2) respectively. The high percentage of PIs with font sizes less than N.10. seen in this study may be due to non-specific nature of the Food Agency guidelines in relation to font size, this regulatory agency did not really emphasize on the readability of inserts in the guidelines for registration of drugs and related products manufacturing in Nigeria.

4.0 CONCLUSIONS AND RECOMMENDATION

Results suggest that package inserts of pharmaceutical and chemical products in Nigeria do not meet up with readability standard. This however implies that there is a lacuna in the general quality of such products in the Nigerian market thus, a ripple effect on health delivery system and infringement on the right to receive information of all kinds.

Food and Drugs Agencies of developing countries typified by Nigeria should be specific in recommendations applying a general font size for optimization, of at least 10-12 pt range of readability in compliance with best global practices for all drugs and chemical products. Compliance and adherence by manufactures to such should also be strictly monitored. Beyond font size, the font type, leaflet size, colour and layout depending on size of the container should be explored. Furthermore visually impaired individuals should be considered in putting the foregoing in place.

CONFLICT OF INTEREST

No conflicting interest.

ACKNOWLEDGEMENT

Many thanks to CASS Pharma Ltd., jos, Pharmacy Dept. BHUTH, Messers Michael Oluseyi Olayinka, Mike Lawal, James Ayorinde, Ikechukwu Omezi, Abayomi Odurinde, Uchekukwu Akaneme and Victoria, Alexander & Alexis T. Ogundeko.

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