

Higher Readability Levels and Suboptimal Design of Medicine Information Leaflets in Artemisinin-based Combination Therapy Antimalarial Packages: A Consequence for Over-the-Counter-Medicines Use

Rachel Obonose Titus^{1*}, Margaret Olubunmi Afolabi¹, Omoniyi Joseph Ola-Olorun¹

¹Department of Clinical Pharmacy and Pharmacy Administration, Obafemi Awolowo University, Ile-Ife, Nigeria

Abstract

The study aimed to determine the readability level and assess the design layout of medicine information leaflets in packages of Artemisinin-based Combination (ACT) antimalarials used as over-the-counter medicines in Nigeria where malaria is endemic with higher adverse events in under-five children and pregnant women. A cross-sectional study design was adopted to evaluate thirty-two medicine information leaflets of ACTs obtained from community pharmacies. Texts in selected passages of the leaflets were subjected to the Flesch-Kincaid (F-K) formula to determine the F-K score and the corresponding reading-grade level. The Baker Able Leaflet Design (BALD) assessment tool was employed to assess the medicine information leaflets design layout. The mean Flesch-Kincaid score for the MILs was 14.22 ±5.06. A proportion of 15.63% of the MILs were readable at the postgraduate level, 28.13% at the undergraduate level, 37.5% at the senior secondary school level and 18.76% at the junior secondary school level. This represented the total proportion of leaflets readable at the junior secondary school level which is the average level of education in Nigeria. On the BALD tool, 46.28% of the MILs were rated 'above standard' and 53.72% were 'poor' in design. The dimension of the longest MIL was 80cm by 36cm. A large proportion of the MILs were written above the reading level of average Nigerians and were poorly designed. Most Nigerians are not likely to be able to read these leaflets for reference purposes and to serve as reminder for instructions obtained during medication counselling.

Keywords: Medicine information leaflets, Readability, Average level of education, Artemisinin-Combination Therapy antimalarials, Leaflet design layout.

Introduction

Information from a professional class using the associated technical language can often be misconstrued or incomprehensible by readers with low and intermediate literacy skills and by those with little expertise on the subject [1]. Medicine information leaflets (MILs) in packages of medicines supplement and reinforce the information received from prescribers and dispensers [2, 3]. They convey information about risks and benefits of individual medicines maximising the medicine's effectiveness and reducing risk of

adverse reactions [4]. The literacy level and the average level of education of persons to which the leaflets are targeted is important in guiding the language and design of the leaflets so that the information is readable to most of them for effective delivery of the intended messages [5-8].

Readability is defined as the level of ease or difficulty with which text material can be understood by a particular reader who is reading that text for a specific purpose, and it is concerned with the problem of matching between text and reader [9]. Also, readability is

concerned with document design where design elements such as type size, line spacing, margins, contrast and colour, and illustrations or graphics are the visual and structural elements of a text that function to enhance and interact to affect the readability of a text [10, 11]. Although the speed of reading is a factor for readability, however, it can be argued that transmitting meaning and keeping the reader engaged till the end of a text are the more relevant features. The style of writing being a high correlate of textual difficulty, information design is pertinent for maintaining readers' interest and promoting understanding of the text [12].

Several texts and authors prescribe the appropriate features of textual characters for documents, labels and package leaflet of consumer goods and pharmaceuticals [13-15]. As opined by Raynor and Dickinson [15], medicine information leaflets should be designed such that headings stand out, typeface are as large as possible, with ample white space, bullets used for lists, statements are conversational with the active voice used, text is non-justified and bold lower case used for emphasis. These text design characteristics make the text more visible, attractive, and easy for readers to find particular information [16-18].

This research presents a novel assessment of medicine information leaflets of antimalarials of the artemisinin-based combination therapies usually supplied as over-the-counter medicines in most malaria-endemic countries including sub-Saharan Africa. Inappropriate readability levels have been globally recognized in texts of materials placed in the public purview [11, 19-21]. The ease of comprehension of the information in medicine information leaflets and the design is important to guarantee that intended benefits are achieved and unnecessary risks in medicines use are avoided. Establishing the reading grade level of texts is usually conducted in advanced countries with the aim of redesigning the text material for easier

comprehension of the larger percentage of the society [22].

According to the UNESCO Institute of Statistics, Nigeria's literacy rate was 62% in 2018 [23, 24]. The universal basic education structure consists of nine years of schooling comprising six years primary school education and three years junior secondary school education [25, 26]. Therefore, reading texts put in the Nigeria public domain should not be above the 9th grade readability level. This is pertinent for medicines like the WHO-recommended artemisinin-combination therapies (ACTs) for the treatment of malaria which are available over the counter for the treatment of malaria and are one of the medicines used in self-medication [27]. According to the World Health Organisation [28], the mode of communication of information provided for medicines is key to responsible self-medication.

Readability Formulas

A readability formula is a simple method to predict the score and reading grade level required to comprehend written materials and documents. Studies on developing readability rating of English Language texts have been around since the 1920's but was given popularity by Flesch [29], Dale-Chall, and Gunning in the 1940's in their publications on readability formulas [16] stimulating new consumer demands for documents in plain language. The readability test formulas are based on the combination of the number of words per sentence and word length [30,31]. As further noted by Adepu and Swamy [7], readability tests are predictors of the reading difficulty or reading ease of a text. The Flesh-Kincaid formula involves three main variables which are the number of words, number of sentences and the number of syllables in a given passage.

The Baker Able Leaflet Design Tool

The Baker Able Leaflet Design (BALD) tool is a summary of the features considered necessary to enhance readability and attractiveness of medicine information leaflets. The tool enumerates text characteristics such as number of colours used, font size of the typeface, use of pictures, tables and italics, the length of the lines and the separation between the lines. Other characteristic features of the leaflet design assessed on the tool are use of Arabic numerals, the percentage of white space and the paper quality. These characteristics are expected to be seen in a leaflet that is of good layout and design [32]. The tool assesses the layout and design of the leaflets using scores allotted to each of the enumerated features on the tool and summing up to yield the BALD score. A leaflet with a BALD score of 25 or more is considered to be of good layout and design [33].

The font size proposed on the BALD tool agrees with other authors' estimates of the acceptable font size which is that the text should be of sufficiently large type not more than 12 and not less than 10 to facilitate readability [34]. The assessment of the number of colours and use of distinctive text sizes reflects the importance of these features which aids navigation and usability of the text [35]. A clear listing of adverse effects, for example, distinguishable with a different colour or bold texts improves the ease of understanding of the message especially when the heading is in lower cases of letters. According to the European Commission Guideline [13] on the readability of the labelling and package leaflet of medicinal products for human use, letters in their lower cases give shape to words, make them easier to recognise and read better than capital letters.

The European Commission Guideline [13] prescribes that the space between one line and the next should be at least 1.5 times the space between words on a line, where practical as it is

an important factor influencing the clarity of the text. The guideline also considered factors like paper weight, colour of the paper, size and weight of the type, colour of the type and the paper itself which are elements included in the BALD tool for assessment of leaflet design.

This study evaluated the readability of the artemisinin-based combination therapies used commonly for the treatment of malaria in Nigeria.

Materials and Methods Materials

All the thirty-two MILs of different brands of ACTs were collected as publicly available secondary data during the course of four months assigned for collection. They were obtained directly from pharmacies in Oshogbo, Ibadan, Lagos and Ile-Ife and by post from pharmacists based on solicitation on a pharmacists' only WhatsApp group platform. They assisted in collecting and sending the leaflets from their shops across the country (Benin-City, Enugu, Ilorin, Jos and Okene).

An evaluation guide was developed to assess the MILs of the 32 ACTs collected. The first section explored independent variables about the leaflets such as the name, strength, whether it was an imported product or locally manufactured, the type of formulation (adult, paediatric or both) and the presentation of the formulation (as a suspension or as tablets). Another section calculated the readability grade level of the leaflet using the Flesch-Kincaid formula. The last section enumerated the 16-item BALD table and the scores for each item was summarized for each MIL.

Methods

The study was a cross-sectional descriptive evaluation of medicine information leaflets of ACT antimalarials used in Nigeria. The Flesch-Kincaid formula was used to calculate the reading age score of the leaflets and the Baker Able Leaflet Design tool was used to assess the design of the medicine information leaflets.

Calculation of the Readability Level of MILs using the Flesch-Kincaid Score

A section of the message of the leaflet that contained about 100 words was selected for calculation of the Flesch-Kincaid Score for each MIL. The layout of the information from one MIL to another is different therefore, passage selected was not dependent on the information type but rather, on the selection was based on any portion of the MIL which contains a rough estimate of 100 words in it. This does not pose any bias to the process since the style of writing is known to be consistent for writers so any passage used is expected to reflect the unique style of writing of each MIL. The number of words, number of sentences and the number of syllables in the selected section were each counted and imputed into the Flesch-Kincaid Readability formula.

Flesch-Kincaid readability formula

$$= 0.39(ASL) + 11.8(ASW) - 15.59$$

ASL=Average sentence length

$$= \frac{\text{Total number of words in a passage}}{\text{Total number of sentences}}$$

ASW = Average syllable per word

$$= \frac{\text{Total number of words in a passage}}{\text{Total number of sentences}}$$

The variables are used to compute the average sentence length (ASL) by dividing the total number of words in a passage by the total number of sentences; and the average syllable

per word, calculated by dividing the number of syllables by the number of words in the passage.

The score obtained is equivalent to the reading level for the leaflet. Each leaflet was subjected to the Flesch Kincaid readability formula and the score recorded.

BALD Evaluation of the MILs

Evaluation of the design of the medicine information leaflets using the BALD tool. For each of the MILs of antimalarial medicines sampled, evaluation of their design using the BALD tool involved the following steps:

The length of the MILs lines was measured in millimetres using a rule placed across the length of the lines of words. If it was between 50-89mm the MIL received a point. If it was less or more, it scored a zero.

1. The separation between the lines was measured also in millimetres. Measurement less than 2.2mm scored a zero, measures between 2.2-2.8mm got 2 points and separations between lines that were more than 2.8mm got 3 points. On this item, there was no indication for scoring one point.
2. The third item on the tool was the justification of the first line. One point was awarded if the first line was unjustified zero to MILs with justified lines.

Table 1. Baker Able Leaflet Design (BALD) assessment tool

Design Characteristics	3 points	2 points	1 point	0 point	Point scored
Lines 50-89 mm long			Yes	No	-
Separation between lines	> 2.8mm	2.2-2.8mm		<2.2mm	-
Lines unjustified			Yes	No	-
Serif typeface		Yes		No	-
Type size	12 points	10-11 point	9 points	< 9 points	-
First Line indented			Yes	No	-
Titles lower case			Yes	No	-
Italics		0 words	1-3 words	≥ 4 words	-
Positive advice		Positive		Negative	-
Headings standout		Yes		No	-

Numbers all Arabic			Yes	No	-
Boxed text			0-1Box	> 1 Box	-
Pictures	Words count not replace	In between	In between	None or superfluous	-
Number of colours	4	3	2	1	-
White space	>40%	30-39%	20-29%	<20%	-
Paper quality	> 90gsm	75-90gsm		< 75gsm	-
-	-	-	Total	-	-

3. The serif typeface which is almost similar to the Times New Romans font style was assessed next. The MIL got a score of two points if the font style was in serif and a zero if it does not.
4. To evaluate the type size, comparison was made with a printed document with texts of different sizes. This enabled the direct assessment of how large or small the text size was. Font size of 12 received 3 points, font sizes of 10-11 received two points, a font size 9 got one point, and text less than 9 received a zero mark.
5. Indentation of the first line was scored one point and zero if indentation was absent.
6. Lower title cases were scored 1 point and zero for capital letters.
7. Words in italics were counted. If no italics were used, the MIL scored 2 points; if between 1-3, one mark was assigned and zero if up to or more than four words were italicised on that item.
8. The text for each MIL were assessed for use of positive words. If positive statements were used, 2 points was awarded. Negatively rendered statements scored zero.
9. If the heading stood out in an obvious way such as with colours or bold text, the MIL received a score of 2 points and if it does not, it receives no score.
10. All numbers are expected to be in the Arabic form in which case the MIL scored one point and if they are not all rendered in Arabic then the MIL scored a zero.
11. If there were boxed text in the leaflet, they were counted. MILs that have 0-1 box

scored one point and those containing more than one box scored a zero.

12. The use of pictures without replacing the text scored 3 points and if the picture appeared in between the text, it scored a 2. If no picture was used or the picture was unnecessary the MIL scored a zero.
13. The number of colours used was assessed by the number of colours used in the MIL. If it was up to four colours the MIL was given a score of 3 points, 2 points if there were 3 colours and one point was awarded an MIL designed with two colours. An MIL designed with only one colour scored a zero.
14. The amount of white space was subjectively judged by the assessor.
15. The Paper quality was judged by making comparisons with different weights of A4 print paper. The researcher obtained papers of different qualities and compared their thickness with that of each MIL.

The total points obtainable is 32. The cut-off point for leaflets of good design is 25 according to the BALD tool estimate.

Results

The MILs Flesch-Kincaid scores.

The average Flesch-Kincaid score for all the MILs was computed to be 14.22 ±5.06. The highest score was recorded for ACTs 30 and 25 (F-K Score= 24.15) and the lowest score for ACT20 (F-K Score = 6.07) giving a range of 18.08 scores. The MILs Flesch-Kincaid scores and the corresponding ages and readability grade levels with respect to their scores are presented in Table 2. A proportion of 15.63% of the MILs are readable at the college graduate

level, 28.13% are readable at the college or undergraduate level, 37.5% of the MILs are readable at the senior secondary school level while the proportion of the MILs readable at the Junior Secondary school and primary school level were 9.38% each.

An ANOVA test of difference between the means of the F-K reading age scores (Table 3) show that there was no significant difference between the MILs of adult and paediatric

formulations ($F = 0.95$, $df = 31$ and $p = 0.399$). The mean weighted averages of the F-K scores of MILs of both imported and locally manufactured products was 24.16. There was no significant difference between the F-K scores of the MILs of locally manufactured products and those of imported ones using independent samples ($t = -1.96$, $df = 30$, $p = 0.06$).

Table 2. MILs Flesch-Kincaid Scores and corresponding grade level

Brand name of Antimalarials	Flesch-Kincaid score	Reading Age/Grade Level	Proportion of MIL (%)
ACT30	24.15	College graduate level (Postgraduate level)	-
ACT25	24.15		-
ACT13	22.68		15.63
ACT32	22.65		-
ACT27	20.04		-
ACT16	18.85	College level (Bachelor's degree holder and HND level)	-
ACT14	17.56		-
ACT10	17.25		-
ACT22	16.8		28.13
ACT11	16.75		-
ACT6	15.97		-
ACT1	15.78		-
ACT23	15.76		-
ACT18	15.14		-
ACT12	14.22		Senior Secondary School Level
ACT4	14.6	-	
ACT9	13.71	-	
ACT8	13.28	-	
ACT17	13.24	-	
ACT5	13.12	-	
ACT7	11.81	37.5	
ACT15	11.15	-	
ACT28	10.85	-	
ACT19	10.01	-	
ACT24	10	-	
ACT29	10	-	
ACT3	9.75	Junior secondary School level	
ACT21	8.56		9.38
ACT26	7.73		-
ACT31	6.88	6th Grade (Primary School level)	-
ACT2	6.66		9.38
ACT20	6.07		-

Table 3. Analysis of variance of means of Flesch-Kincaid scores across product formulation group

	Sum of Squares	df	Mean Square	F	p
Between Groups	48.71	2	24.35	0.95	0.39
Within Groups	743.53	29	25.64		
Total	792.24	31			

The Baker Able Leaflet Design assessment

Figure 2 shows the BALD assessment scores of the MILs. The BALD assessment scores of all the MILs lie between 10.0 and 19.0 (Table IV). The highest score (19) was recorded for ACT 31 Dispersible tablets while the lowest score of 10 was for ACT27 and ACT11 giving a range of 9. The average BALD assessment score was computed to be 13.38. The modals core was 13(25%). The mean BALD

assessment score for the MILs was significantly lower than the lowest allowable point of 25 ($t=3.77$, $df=31$, $p=0.001$) (Table 5). Out of the thirty-two MILs 15.63% recorded above average scores on the BALD tool of 32 points while 84.38% of the MILs recorded less than average scores. They all fell under the category of “poorly designed” MILs as shown in Table V.

Table 4. BALD assessment scores of MILs grouped into levels of acceptability

Brand name of Antimalarials	BALD score	Design and Layout
ACT31	19	Poorly designed (above Average but below standard <25point)
ACT17	17	
ACT32	17	
ACT26	16	
ACT4	16	
ACT12	15	Poorly designed (below average and below standard)
ACT1	15	
ACT5	15	
ACT3	15	
ACT28	14	
ACT20	14	
ACT7	14	
ACT10	13	
ACT18	13	
ACT15	13	
ACT13	13	
ACT2	13	
ACT24	13	
ACT29	13	
ACT6	13	
ACT23	12	
ACT22	12	
ACT8	12	
ACT28	12	
ACT21	12	
ACT16	12	

Brand name of Antimalarials	BALD score	Design and Layout
ACT14	12	
ACT9	11	
ACT30	11	
ACT30	11	
ACT27	10	
ACT11	10	

Table 5. Inferential statistics of the BALD score for the MILs (One-Sample t-Test)

	Sample test value	t	df	P	Mean Difference
Baker Able leaflet Design Scores of the MILs	25	3.77	31	0.001	2.81

Significant at $p < 0.05$

Discussion

The MILs Flesch-Kincaid scores showed that more than 80% of the MILs can only be read and understood by persons with a level of education higher than the average level of education in Nigeria. The results agree with previous studies that showed that some MILs were written at levels far above the average educational level of the general public. This is with implication according to [7] and [36] that many consumers who should benefit from the use of the information might not be able to understand it. They are faced with the choice of using the medicine with poor understanding of the written instructions. For the keen information seeker, essential time is expended in trying to find persons who can read and explain the information to them.

On the BALD tool, the MILs scored below the minimum 25-point benchmark for a leaflet of good design indicating that they all were poorly designed. This infers a serious defect in the design of the leaflets because they are not designed in a way that captures the attention of a reader. Studies such as those by [37-39] have shown that many readers would be put off reading the text or discouraged to read further when the document is poorly designed. For example, if the font sizes are too small for consumers to appreciate the letters or if pertinent information are not distinct from the rest of the text, many would not be able to

navigate the leaflet to access the information [40].

Though it may be argued that some of the criteria in the BALD tool may be stringent to apply, for example, a score of 3-points for paper thickness of 100gsm might well be an idealistic criterion as papers of such thickness are often commonly used as formal letter head papers and might be difficult to fold into a medicine package. Economic considerations and packaging convenience could also preclude use of papers of such thickness in the printing of MILs and also inform the tight spacing of words to reduce the amount of paper used. This difficulty, and that posed by guidelines requiring ‘plenty of white space’, according to [41] seem subsumed in the bid to avoid too lengthy MILs. Economic considerations could also explain why different colours are not used in most of the MILs. However, as posited by proponents of readability like [42], when reading interest has to do with the design of a document text, readers are put off reading a text when the document is poorly designed. Thus, there is a hindrance in the communication process.

The consequence of this is that intended information is not being harvested though the reader has access to it. Furthermore, the benefits of using the information are lost to the consumer and a misuse of the medicine could result when no other means of transmission of

the necessary information is available. A graver impact for such misuse is precipitation of adverse reactions and toxicities which could otherwise have been prevented if the medicine information leaflet was well designed. The situation calls for an improvement in the design of these MILs.

Conclusion

This study shows that the readability of the MILs of ACTs used in Nigeria in terms of reading grade level and the design of MILs are not adequate. The readability level was not adequate for the majority of readers as only highly literate individuals can read most of the MILs with ease. The design and layout of the MILs were also unacceptable based on the BALD assessment.

Recommendations

From the outcome of this study, the following recommendations are suggestions for improvement of the MILs of ACT antimalarials in Nigeria.

1. Manufacturers and importers of ACT antimalarials to Nigeria should present the MILs in a shorter and more easily understood format for the consumers.
2. Developers of medicine information leaflets should consider using the BALD assessment to evaluate their design for a more acceptable MIL.
3. Developers of MILs should consider adopting the style of having two separate sections in the MILs, one for health professionals who prescribe, dispense, and

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administer medicines, and the second section presented in very simple language for lay medicine consumers.

4. The National Agency for Food and Drugs Administration and Control (NAFDAC) the drug and food regulatory body in Nigeria should institute readability tests for medicines available as OTCs before awarding approvals to marketers in which important safety and efficacy information in the MIL is found to be comprehensive by at least 80% of the participants.

Limitations of the study

The study was limited to an evaluation of MILs of ACT antimalarial medicines. Further studies could evaluate the MILs of other classes of medicines.

Ethical approval

There are no human subjects involved in this study and the medicine information leaflets were publicly available. Hence no ethics approval was sought for the conduct of the study.

Conflict of interest

The authors have no conflicts of interest to declare.

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