Scientific Research Publishing

Open Journal of Applied Sciences, 2023, 13, 775-792
https://www.scirp.org/journal/ojapps
ISSN Online: 2165-3925
ISSN Print: 2165-3917

# Reading Levels of Leaflets of Common Over-the-Counter Drugs in Ghana

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**How to cite this paper:** Gyasi, W.K., Owusu- Ansah, L.K. and Frimpong, M.A. (2023) Reading Levels of Leaflets of Common Over-the-Counter Drugs in Ghana. *Open Journal of Applied Sciences*, **13**, 775-792.
https://doi.org/10.4236/ojapps.2023.135062

**Received:** January 23, 2023
**Accepted:** May 28, 2023
**Published:** May 31, 2023



## Abstract

Health communication is critical component of effective health delivery. While there are studies on the readability Patient Information Leaflets (PILs) around the world, so far, there is only one Ghanaian study that explored the language of patient information leaflets for malaria. The present study explores the language of PILs of seven common ailments in Ghana. In all, 68 leaflets were purposely sampled for the study. Using SMOG and Flesch Kincaid grade level readability formulae, the researcher measured the readability of PILs and discovered that the readability of all the PILs was difficult to read except the dewormer leaflets that scored standard reading score. Further statistical analysis reveal that the lexical and syntactic complexity of the leaflets were not statistically different. Finally, an interview with 20 patients confirmed that the leaflets are difficult to read due to the complex words and long sentence structures. It is recommended that the PILs be revised to make the leaflets readable.

## Keywords

Health Communication, Readability, Lexical Density, Syntactical Complexity, Readability Formula, Patient Information Leaflets

## 1. Introduction

Humans desire good health because it is the best way to live for long. Quality health care delivery requires effective communication between practitioners and patients. Public service announcement through the use of information centres, national media and outdoor media is not new in the Ghanaian society. Information on sanitary practices, hygienic practices and precautionary and preventive measures are communicated through the public service an-

nouncements [1].

Bernhardt found that the relationship between communication and health has rapidly developed and expanded [2]. Health communication involves strategic dissemination of relevant health information to influence behavioral change among people [2]. Health communication could be done through print, verbal, multimodal and other effective formats. Patient Information leaflet is a print health communication document.

Patient Information Leaflets contain information about the drug or medication from manufacturer to consumer. It is obligatory to put package leaflets in all medicine packages. It is expected read the leaflets to know more about the drug and how to use it well for maximum results. The use of clear and precise language is the key to the development of effective and appropriate material.

McLaughlin defines readability as "the level at which particular individuals find a particular text captivating and understandable" [3]. Readability enhances writer's effective communication with readers as well as the level of comprehension of text by a reader. Through the use of readability formulas, manufacturers could have an objective idea of the reading ease level of their patients' information leaflets. Since medical terminologies and technical writing are unavoidable in PILs, the need to guard that through readability scores is advisable.

## 2. Statement of Problem

Patients' information leaflet is a key information document for patients in the absence of health professionals. However, available studies on leaflets have indicated that they are difficult to read and understand. In UK, Williamson and Wilson found the readability of patient's information leaflets above patient's comprehension [4]. In midwestern urban area, Wilson found that patients' information leaflets were written too high for the less educated adult [5]. Also, Bradley *et al.* studied the readability of the leaflets of over-the-counter (OTC) drugs and found that reading score is above the mean reading age of the general adult population [6].

The only known study in Ghana on PILs is by Gyasi, which was on common malaria drugs used in Ghana [7]. Gyasi found that the PILs of the drugs were difficult to read [7]. While his study was based on only malaria information leaflets, there is no other known study in Ghana that explored the readability of information leaflets for common ailments. There is the need for further studies to consider other common ailment in Ghana information leaflets to ascertain their readability and comprehensibility to patients. This is crucial because issues regarding the use of medicine are a matter of life and death. Moreover, there is no known study in Ghana yet that examined the readability of the patient information leaflets and the comprehensibility difficulties readers face in using the leaflets for relevant information about the drugs they use to treat common ailments.

The purpose of this study is to examine the readability and comprehensibility

of Patients Information Leaflets of over-the-counter drugs of seven (7) common illnesses in Ghana. These illnesses are common cold (flu or catarrh), cough, body pains, diarrhoea, heartburns, sleeplessness and constipation. These illnesses are usually treated through the use of over-the-counter drugs from licensed medicine sellers.

## 3. Research Questions

1) What are the readability levels of PILs of OTC drugs when measured in terms of readability formulae?

2) Are there statistically significant differences in the lexical density and syntactic complexity of PILs of OTC drugs across illnesses?

3) Do consumers read PILs of OTC drugs and if they do, do they understand what they read?

4) Is there a correlation between the readability of PILs of OTC drugs and consumers response?

## 4. Literature Review

Communication is the transmission of a message from a source to a receiver [8]. Dominick defined communication as a symbolic, interpretive, transactional process through which meaning is shared among people [8]. Communication as a process involves a series of interconnected stages or events that lead to effective communication. These stages are normally regarded as the elements of communication process [9]. The elements include source, message, channel, receiver, feedback and noise.

One element of the communication process that could hinder the success of effective communication is noise. Noise is anything that affects message effectiveness. Shannon and Weaver as cited in Dominick categorized noise into physical, mechanical and semantic noise [8]. In reducing semantic noise, assessing the readability of the written PILs of common illness drugs is indispensable. Hence, the need for readability studies on PILs.

Patient Information Leaflets are written documents that contains information about a drug especially its composition, use, side effects and producers [7]. This information leaflets are usually inserted in the drug package or box for users to read and know more about the drug. There are three types of medications that patients could purchase for treating different ailments. These include Prescription Only Medications (POMs), Pharmacy Medicines (PMs) and over-the-counter medications (OTCs). The prescription only requires medical professionals, and to the most extent pharmacy medicines. But over-the-counter medications are sold by licensed drug sellers for patients to purchase. Because the dealers of over-the-Counter drugs are not professionals, the patients might have to rely on the PILs for relevant information about the drug. OTCs are the drugs that any individual can walk into any of their sales points and purchase without a prescription or a pharmacist being around. There are very accessible and self-prescribed by patients.

Since the tendency to use technical terms and expressions in PILs is high, there is the need to consider the language of PILs. Lexical density and grammatical complexity are key features for making the leaflets readable and understandable. Lexical density is the estimate of the percentage of lexical items in a piece of writing [10]. Halliday is of the view that the percentage of the number of lexical items as against the running words is lexical density [10].

Moreover, syntactic complexity is a measure of how complex or dense the grammar used in a piece of text is. It is noted that sentences are progressively sophisticated with increases in complex modifications such as modifiers, verbs in serial expression, among others [11]. The syntactic and lexical density usually culminates to reading difficulty of a text: readability.

Readability studies focus on the reading difficulty of a text based on the syntactic and lexical features of the text [12]. Readability determines the level of ease reading the text. Mostly, readability of text is measured using readability formulae. According to Zamanian and Heydari, ability to predict text readability is useful because it helps educators to select appropriate texts for students as well as authors to write texts suitable to the audience they target [13]. In an attempt to device ways of predicting readability of a text, readability scholars have developed readability metrics to this effect. There are over 200 readability formulas today which can be used to predict how readable a text is to read [13] [14]. These formulae include SMOG, Flesch reading ease, Flesch Kincaid grade level among others.

Readability influence comprehension very positively. According to DuBay, readability is determining factor that withhold reader's interest to read an article that is not interesting [13]. In order words, when reader's interest is low, readability contributes highly to text comprehension. The general assumption is that a readable text is most likely to be comprehensible for most readers, especially if it is written in the standard grade level which is the grade that is recommended for public documents [14]. Nevertheless, readability resides with the text while comprehension resides with the reader. Worded differently, readability depends on text characteristic while comprehension depends on reader abilities. Therefore, readability influences comprehension if the text variables meet the readers abilities.

There have been studies on readability and patient information leaflets around the world. Clerehan *et al.* assessed the quality of written PILs using SFL theory as a guide [15]. The authors sampled 18 Leaflets of Rheumatoid arthritis. They discovered that the lexical density was moderately high (5.0). They recommended that PILs be revised. This implies that the reading difficulty of the leaflets stemmed from the lexicals which mostly likely is due to the technical words.

In another study, Musacchio compared Italian and English PILs. The author selected 14 Leaflets of Colds and flu [16]. Musacchio found that the Italian leaflets were denser (60%) than English leaflets (52%) [16]. Also, Musacchio discovered that Italian texts used nominalization, specialized words and prepositional phrases that made them complex than the English leaflets [16]. In patient centered study, Hirsh et al who sought to obtain patients' feedback about the struc-

ture and quality of PILs [17]. They used Evaluation Linguistic Framework (ELF) to examine the views of 50 Australian patients. The authors used interview and self-administered questionnaire to collect data. Hirsh *et al.* found that PILs reinforced the messages communicated by doctors to patients [17]. The participants found some medical terms to be terrifying which scared them off from reading the leaflet. The participants found the leaflets complicated and too "densed" making it difficult for them to find the information in them. So far, these available studies on the lexical density and syntactic complexity found the PILs densed and complex for readers. Travedi *et al.* examined the product labels of 40 non-prescription medications for readability and comprehensibility. Using Flesch reading, the authors found the leaflets to be above the reading grade level of public documents. The qualitative assessment of the leaflets revealed severe deficiencies such as poor organization and inundation with technical terms were found. They asserted the need for considerable improvement in the readability of these labels. Alanqueel and Obaidi in their study of 100 Arabian PILs found that complex to read [18]. Likewise, Kasesnik and Khine analyzed 1474 of Slovene leaflets and found that they were very difficult to read with Flesch reading ease score of 5.

Auta *et al.* assessed the readability of 45 malaria medicine information leaflets obtained from community pharmacies in Jos, Nigeria [19]. The leaflets were of attention based preparation of antimalarial and the assessment was made in relation to the paper type, font type and size, use of symbols and pictograms and bilingual information. SMOG readability formula was used to assess the readability of the leaflets. The data was fed into Microsoft Excel 2007 spreadsheet containing the readability test formula (SMOG) to generate readability grade level for each leaflet. Their findings were that, malaria medicine information leaflets in Nigeria health sector are not readable to the average reader in Nigeria. This is because the readability grade level ranged from 9 to 16 with 14 as the top reading grade level. The mean grade level was 13.69 with a standard deviation of 1.70. It was also noted that 6.7% of the leaflets were glossy and contained symbols and pictograms, 57.8% of the leaflets had a font size less than 8 which is considered the absolute minimum acceptable font size for medicinal leaflets in European countries (which this study also adopted) while just about 2.2% of the leaflets were written in both English Language and a major language in Nigeria. This means that most of the malaria medicine information leaflets are not readable to a better part of the Nigerian populace since a good number of the leaflets sampled required a tertiary level of education to comprehend them. They however recommended that these leaflets should be made readable since their migration from Prescription Only Medicines (POMs) to Over-The-Counter (OTC) as a way of promoting home management of malaria. To make the leaflets readable and useful, they should be produced in the consumers primary language since about 54% men and 74% women in Nigeria can read in one of the major languages. Instead, these leaflets are produced in English and French when only a few of the populace can read French. It is also their hope that policies will be put

in place to design non-technical consumer information leaflets as other developed countries are practicing.

A study was also conducted by Gyasi on the readability of patient information leaflets of Malaria drugs in Cape Coast, Ghana [7]. Seven leaflets of commonly used malaria drugs in the Cape Coast metropolis were sampled. The Flesch Kincaid reading ease and the Gunning Fog indexes were used to assess the readability of these leaflets. He found out that all the patient information leaflets sampled were difficult to read and defied their purpose. The Flesch Kincaid Reading Ease showed values ranged from 10.4 to 36.3 which is equivalent to university education grade and a Gunning Fog score 14.2 to 18.8 which exceeds the grade level requirement for university graduate readers were the results obtained from the formulas. When the leaflets were tested for legibility, it was noticed that most of the leaflets were written with font size less than 10 which implied that they were generally not readable especially to those with sight problems. However, when the leaflets were tested for type of paper used, it was revealed that they were non glossy and non-coated papers which are very good because they enhance reading. Bilingual data analysis indicated none of the leaflets were written in any of the local languages in Ghana but a small quantity was written in only English Language with majority of the leaflets written in English Language and an international language which is not beneficial. Testing the leaflets for pictorial illustrations, none of them had pictures to enhance comprehension which was not helpful. Gyasi recommended that since malaria drugs are now over-the-counter medicines, their leaflets should be produced to suit the readability and comprehensibility level of the average Ghanaian [7]. He therefore encouraged the Ghana Health Services and the Food and Drugs Authority to formulate and enforce policies to that effect. It is actually the work of this researcher that necessitated this study. Since much work have not been done on readability of these PILs in Ghana for the appropriate entities to read their outcome and address issues raised, this study is to add a voice to the only existing literature in Ghana by assessing the readability of PILs of common drugs for common illnesses bought over-the-counter. If any generalization can be made or any conclusion can be drawn as per other parts of the world where studies are scanty and have been found that these health materials are not readable, Gyasi's study was limited in scope for that since he worked on only 7 PILs of malaria drugs [7]. This research will assess the readability of 100 PILs for ten common illnesses. It will also go the extra mile to interview consumers of these OTC drugs to find out from them if they read the PILs and if they do, whether they understand what they read. I believe the scope of this research is broader enough for any generalization to be made if the need arises. It is the hope of the researcher to make useful findings and then continue to make relevant recommendations for the intended purpose of these leaflets to be achieved. To coordinate these distinct studies, that is text-centred studies and patient-centred studies, the current study measures the readability using the readability formulae as well as views from twenty patients.

## 5. Theoretical Framework

In the words of Pikulski and Chard, "as part of a developmental process of building decoding skills, fluency can form a bridge to reading comprehension" [20]. As the co-authors cited the definition of Reading Panel (National Institute of Child Health and Human Development), fluency is "the ability to read text quickly, accurately, and with proper expression" [20]. However, the authors pointed out that such a definition emphasizes fluency as an oral reading phenomenon and this has limited the attention given to fluency in reading comprehension. According to Harris and Hodges, fluency is "freedom from word identification problems that might hinder comprehension" [21]. This definition of fluency has enlarged it to cover comprehension. It is therefore on this notion of fluency that pioneers of fluency theory such as Samuel, Stecker, Roser, and Martinez, based their postulations [21].

According to Stecker, Roser, and Martinez, "fluency has been shown to have a 'reciprocal relationship' with comprehension, with each fostering the other". Therefore, reading fluency refers to efficient, effective word recognition skills that permit a reader to construct the meaning of a text. Pikulsi and Chard identified two construct of fluency which are surface construct and deep construct [20]. A surface construct of fluency builds on an oral prosody of oral reading while a deep construct views fluency far more broadly as part of a developmental process of building decoding skills that will form a bridge to reading comprehension and that will have a reciprocal, causal relationship with reading comprehension. Fluency builds on a foundation of oral language skills, phonemic awareness, familiarity with letter forms, and efficient decoding skills.

Ehri's theory of stages of reading development and fluency is one elegant theory on fluency. According Ehri, there are four stages of reading development and fluency which are pre-alphabetic stage, Partial alphabetic stage, fully alphabetic stage and Skilled reading level [22]. At the pre-alphabetic stage, readers lack understanding of alphabetic principle which is letters and their sounds and hence have difficulty pronouncing and except by doing association of letters based on their visual components such as Monkey, the "y" tail represents the monkey's tail. This is problematic if there is error in the visual association such as "my". In the partial alphabetic stage, readers learn the letters and their sounds but their knowledge of sounds are limited hence they can find it difficult to pronounce unfamiliar words. Fully alphabetic stage is where readers have the ability to use pronunciation and hence can pronounce unfamiliar words based on the sounds combinations. This however, may not be fluent readers as in reading fast. The skilled level is where readers develop the skill of knowing words by sight. At this stage, readers can read fast. Ehri identified building graphophonic foundations for fluency [22]. These are letter familiarity, phonemic awareness and knowledge of graphemes typically represent phonemes in words. Ehri's theory made the decoding process as dependent on readers ability to develop their reading fluency.

One aspect of Ehri's postulation that is of great importance to readability studies is the addition of language skills to graphophonic skills as a requirement for success in fluency of reading comprehension among readers. Ehri's theory requires a foundation in language skills so that students (readers) are familiar with the syntax or grammatical function of the words and phrases they are reading and with their meanings [22]. According to Ehri, one of the greatest challenges facing educators is developing the oral language and vocabulary skills of children, particularly those who are learning English as a second language or those who spent their preschool years in language-restricted environment [22]. She further asserts that highly frequently used words such as the, of, at among others help readers develop vocabulary skills.

The relevance of fluency theory to the present study is therefore clear. A readable text is a text that is composed with readers in mind. The author of the text tries to make use of familiar words and phrases as well as plain language, so as to enhance readers' comprehension. Ehri's fluency theory is therefore apt as the theoretical framework for this study [22]. The theory is to guide the researchers' argument of how lexical density and grammatical complexity can be possible causes of readability problems of health information leaflet. Also, because the theory acts as a bridge between the readability if a text and the comprehension of the same text to readers, it makes it suitable for the present study since the study has readability and comprehensibility as key variables in the study.

## 6. Research Design

The nature of this study indicated that a non-experimental descriptive approach was the appropriate design. In a non-experiment study, such as this one, there is neither controlling for nor manipulation of some phenomenon of interest and then measuring the effect or outcome of such control or manipulation [23]. Descriptive research rather involves making observations of a phenomenon of interest and recording these observations as they are presented. In this work, observations of the reading difficulty levels of the CMI/PILs were made via online readability testing, and the quantitative scores were recorded. The means of the readability scores of the groups were compared; but the comparison did not preclude the study from being descriptive.

Seven groups of CMI/PILs were tested for reading difficulty. The documents were grouped according to the ailments or conditions for which their respective medicines were indicated. The medicines fell under these types: appetite stimulants, cold and flu medicines, cough preparations, dewormers, gastrointestinal reflux relievers, haematinics, and pain medication. Each leaflet was published by the manufacturer of the respective medicine. The leaflets came in a variety of font styles and sizes, document lengths, font colours, and quality of paper.

The package leaflets were conveniently sampled. With proper permission, and the help of a certified pharmacist, the researcher collected package leaflets from

patients who bought medication from the OPD Pharmacy of the Cape Coast Teaching Hospital. Over the collection period, a total of 100 were collected. However, after sorting it was found that some of the leaflets were the same, hence the researcher used 68 leaflets. The extra leaflets were culled from the collection. Each document was scanned into a jpeg file at a high dot-per-inch setting using a hand-held SkyPix TSN410 Handyscan scanner. The scanned documents were individually converted to editable text by means of ABBYY Screenshot reader, an optical character recognition (OCR) software.

Blocks of text were selected from each document for readability analysis. The text selection was criterion-based. Criterion-based sampling, also known as judgmental sampling, is a non-probability process wherein cases sampled are selected on the basis of the researcher's typicality, the researcher's judgment, or otherwise on predetermined criteria. A primary criterion for selecting text was based on the findings of Raynor *et al.* that the parts of medicine information leaflets that were most likely to be read were, in that order, side effects, administration, and indication. A three-decade old study had shown that the items on a packet leaflet most likely to be recalled by patients were directions for use and side effects or adverse reactions. The side effects, administration, and indications sections respectively provide information on possible adverse reactions to the medicine, how and when to take the medicine, and what conditions or ailments the medicine is intended for. In keeping with the finding of Raynor *et al.*, I selected the following sections for inclusion in sampled text: *Indications*, *Contraindications*, *Adverse Reactions*, *Warnings and Special Precautions*, *Overdosage and Treatment*, *Dosage*, and *Pregnancy and Lactation*. Where available, texts from sections such as *special populations* were also included in the readability analyses. Based on my subjective judgment, I excluded sections such as *pharmacological actions* and *pharmacokinetics* from the analyses; these routinely contained many technical jargons and appeared to have been written for the benefit of health professionals and not the average patient.

In cognizance of the fact that bulleted lists, tables, equations and headings were not among the materials used to develop the formulas, I cleaned the sampled texts to remove headings, and to replace contractions, abbreviations, elisions, and initialism with their full forms. For in instance, "etc." was replaced by "and so on"; "%" was replaced with "percent"; and "mg" was replaced with "milligram(s)".

## 7. Readability Analysis

Each final sample was analysed for readability using the online calculator at https://www.readabilityformulas.com. While the calculator returned readability scores from eight different indexes, I only recorded scores for SMOG and Flesch-Kincaid. Other data I recorded were: word count of sampled text, average number of words per sentence, average number of syllables per word, and percentage of multisyllabic words (≥3 syllables). These methods were complemented

by Graesser, McNamara, Louwerse, and Cai's Coh-metrix tool which is used to measure the cohesion and linguistic features of text based on the sentence and word features [24].

## 8. Lexical Density Analysis

The sampled texts were tested for Lexical Density using the online calculator found at https://www.online-utility.org/text/analyzer.jsp. The data was recorded in the same MS Excel worksheet as those from the readability tests.

## 9. Results of the Study

The first research question examined what are the readability levels of PILs of OTC drugs when measured in terms of readability formulae? From the results, it was discovered that the PILs of appetite stimulant was found to be difficult to read. They had a readability consensus mean score of grade level was 14$^{th}$ grade. This implies that reader should have attained at least fourteen years of formal education to find the PILs easy to read and understand. In general, the PILs for appetite stimulant had high reading grade level.

Also, the PILs of cold and flu was found to be difficult to read. The readability consensus means score of grade level was 13$^{th}$ grade. This implies reader should have attained at least thirteen years of formal education to find the PILs easy to read and understand. In general, the PILs for cold and flu had relatively high reading grade level. This study confirms the work of Musacchio who cold and flu PILs to be complex [16]. Moreover, the PILs of cough was found to be difficult to read. The readability consensus means score of grade level was 11$^{th}$ grade. This implies reader should have attained at least eleven years of formal education to find the PILs easy to read and understand. In general, the PILs for cough had relatively high reading grade level.

For dewormers, the dewormer medicine PILs were written at an appropriate reading grade level according to the Flesch Kincaid grade level of 7$^{th}$ grade. But the readability consensus score was at 15$^{th}$ grade meaning very difficult to read. This implies readers should have attained at least 14 years of formal education to find them easy to read. Also, the PILs of gastrointestinal reflux medicines were found to be difficult to read. The readability consensus means score of grade level was 13$^{th}$ grade. This implies reader should have attained at least thirteen years of formal education to find the PILs easy to read and understand. In general, the PILs for cold and flu had relatively high reading grade level.

The PILs of haematinics was found to be difficult to read. The readability consensus means score of grade level was 13$^{th}$ grade. This implies reader should have attained at least thirteen years of formal education to find the PILs easy to read and understand. The PILs for haematinics had relatively high reading grade level. Also, the PILs of pain was found to be difficult to read. The readability consensus means score of grade level was 11$^{th}$ grade. This implies reader should have attained at least eleven years of formal education to find the PILs easy to

read and understand. In general, the PILs for pain had relatively high reading grade level.

In all, the results of the readability levels of the PILs of OTC drugs were found to be difficult to read. Except the dewormer PILs that scored appropriate reading grade level of 8th in FKG level, the rest of the PILs above 10th grade. This implies the readability levels of the PILs were above the standard reading grade level which is 8th grade. This study confirms the work of Gyasi who found PILs of malaria to be difficult to read [7]. Likewise other studies elsewhere, thus Nigeria, Italy etc, found readability of PILs to be difficult to read, usually above the standard reading level [18] [19] (**Table 1**).

The table covered the distribution of scores of each PILs as well as showed how the standard and mean scores of the PILs. The mean scores represent an average of the total scores of the number PILs measured for each ailment. The maximum and minimum indicate the highest and lowest score of all the scores in each category of leaflets measured for each ailment.

The second research question deals with what are statistically significant differences in the lexical density and syntactic complexity of PILs of OTC drugs across illnesses? Effort was made to test to see if the mean readability scores for the various groups as determined by the SMOG and Flesch-Kincaid formulas differed from each other statistically. This was done by means of the inferential statistical procedure known as Analysis of Variance (ANOVA).

**Table 1.** Readability scores of the PILs of the common ailments.

| PILs | Measure | N | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|---|
| Appetite stimulants | SMOG score | 11 | 9.1 | 14.6 | 12.336 | 1.5977 |
| | Flesch-Kincaid Score | 11 | 10.8 | 17.9 | 14.218 | 1.9818 |
| Cold and flue | SMOG score | 11 | 9.1 | 14.6 | 12.336 | 1.5977 |
| | Flesch-Kincaid Score | 11 | 10.8 | 17.9 | 14.218 | 1.9818 |
| Cough | SMOG score | 9 | 9.7 | 13.9 | 11.067 | 1.4958 |
| | Flesch-Kincaid Score | 9 | 10.1 | 16.1 | 12.778 | 2.0278 |
| Dewormer | SMOG score | 9 | 7.9 | 14.9 | 12.311 | 2.0763 |
| | Flesch-Kincaid Score | 9 | 7.7 | 16.6 | 13.689 | 2.7374 |
| Gastrointestinal Reflux | SMOG score | 8 | 8.8 | 13.6 | 12.175 | 1.7044 |
| | Flesch-Kincaid Score | 8 | 10.8 | 16.5 | 14.188 | 1.9881 |
| Haematinics | SMOG score | 7 | 10.8 | 12.7 | 11.771 | 0.6499 |
| | Flesch-Kincaid Score | 7 | 11.5 | 15.7 | 13.500 | 1.4048 |
| Pain | SMOG score | 17 | 7.4 | 15.6 | 12.194 | 2.0714 |
| | Flesch-Kincaid Score | 17 | 8.0 | 19.3 | 14.312 | 2.6351 |

In order to determine the proper ANOVA procedure to use in this test, it was imperative to make sure that the data fulfilled certain assumptions or otherwise. These assumptions included a normality of distribution of the data sets, and a homogeneity of variance among the means. The normality of distribution assumption was tested by means of the Shapiro-Wilk statistical procedure. At 0.05 significance or alpha level, the data sets were found to be normally distributed. Levene's statistical test was used to assess the homogeneity of variance among the mean readability scores. At the 0.05 alpha level, the population variances of the PILs groups were found to be equal. Results from these preliminary tests indicated that the data sets met the assumptions required to conduct a parametric Analysis of Variance of the mean readability scores. Table 2 presents the results of the ANOVA test.

At the $p < 0.05$ level, there were no significant differences in the readability scores among the seven groups of PILs as measured by the SMOG index [$F(6, 61) = 0.767$, $p = 0.599$] (see Table 2). At the $p < 0.05$ level, there were no significant differences in the readability scores among the seven groups of PILs as measured by the Flesch-Kincaid Grade Level index [$F(6, 61) = 0.700$, $p = 0.650$]. These results mean that, statistically speaking, all the 68 package leaflets were generally written at about the same difficulty level. Since the readability scores did not differ significantly from each other, it is likely that in the real world an average reader will have approximately as much difficulty reading any of the package inserts.

Certainly, the poor readability of the medicine information leaflets as determined by the SMOG and Flesch-Kincaid indices is a cause for concern. The poor readability of the texts may even discourage patients from engaging with the reading materials to begin with. However, readability formulas have their shortcomings. For example, it is argued that they only measure surface level characteristics of texts. For this reason, other concepts and methods of assessing the accessibility of texts are also in use. The next sub-section discusses the lexical

**Table 2.** Analysis of Variance of readability scores.

| | | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|---|
| SMOG score | Between Groups | 14.060 | 6 | 2.343 | 0.767 | 0.599 |
| | Within Groups | 186.390 | 61 | 3.056 | | |
| | Total | 200.450 | 67 | | | |
| Flesch-Kincaid Score | Between Groups | 21.568 | 6 | 3.595 | 0.700 | 0.650 |
| | Within Groups | 313.084 | 61 | 5.133 | | |
| | Total | 334.652 | 67 | | | |
| percentage of multisyllabic words (3 and above) | Between Groups | 106.396 | 6 | 17.733 | 0.609 | 0.722 |
| | Within Groups | 1776.118 | 61 | 29.117 | | |
| | Total | 1882.515 | 67 | | | |

density of the PILs tested in this study. It must be borne in mind that the sample texts used in the lexical density analyses were treated the same as were used in the readability formula analyses.

### 9.1. Lexical Density of the PILs of the Seven Groups of OTC Medicines

Table 2 presents a quantitative description of the lexical densities of the seven groups of PILs tested in this study. In this study, Ure's redefinition of lexical density was employed. According to the definition, lexical density is a ratio of lexical items to grammatical items expressed as a percentage. This means that the lexical density values in Table 2 are percentages of words in sampled texts that have lexical or meaning-bearing value.

As seen from Table 3, the appetite stimulant package inserts scored a mean lexical density of 59.8809 (SD = 7.17752). The highest mean lexical density score was recorded for the PILs that accompanied over-the-counter cough medicines (Mean = 64.9522, SD = 8.92367). At 51.9467 (SD = 7.52005), the PILs accompanying the dewormers scored the lowest mean lexical density. Perhaps this can be explained by the fact some PILs in the dewormer group scored as low as 37.97 of lexical density. Meanwhile, the cold and flu medicines information leaflets recorded the widest variations in their lexical density scores with a standard deviation of 12.59833 for a mean of 61.0314.

Because lexical items are the information components of a sentence, a text with higher lexical density has more information, and therefore carries more meaning, than one with lower lexical density [16]. The concept of lexical density is related to the notion that the greater the information load of a text, the greater that text's demand on working memory, and therefore, the more difficult that text is to understand and recall. On the other hand, the lower the lexical item proportion of the text, the lower the lexical density, the lower the text's demand on working memory, and the easier the text is to understand and recall [16] [19]. Spoken text has lower lexical density relative to written text. This suggests that written text is generally more difficult to process and recall than spoken text.

Table 3. Quantitative description of Lexical Density of PILs.

| | N Statistic | Minimum Statistic | Maximum Statistic | Mean Statistic | Std. Deviation Statistic |
|---|---|---|---|---|---|
| Appetite Stimulants | 11 | 50.87 | 72.78 | 59.8809 | 7.17752 |
| Cold and Flu medicines | 7 | 46.29 | 84.21 | 61.0314 | 12.59833 |
| Cough preparations | 9 | 45.65 | 76.14 | 64.9522 | 8.92367 |
| Dewormers | 9 | 37.97 | 62.69 | 51.9467 | 7.52005 |
| Gastrointestinal reflux relievers | 7 | 50.80 | 63.34 | 56.6771 | 4.70945 |
| Haematinics | 7 | 45.25 | 71.90 | 57.9500 | 10.02754 |
| Pain Medication | 17 | 40.61 | 69.83 | 56.6565 | 9.94186 |

According to a categorization by Sholichatun, there are three levels of lexical density for written texts: high (60% - 70%), medium (50% - 60%), and low (40% - 50%). Guillén Galve found that while lexical density of everyday written text might average 40%, scientific writing might have lexical densities as high as 55% - 75% [11]. Against these considerations, the PILs tested generally have medium to high lexical densities. In fact, the "Maximum" statistic shows that in every group of PILs there were those with very high lexical densities, with some in the cold and flu medicine group going as high as over 80%. According to the mean percentages recorded in **Table 2**, the PILs for the appetite stimulants, the cold and flu medicines, and the cough preparations have high lexical densities mostly. This means that they generally will offer the greatest processing load to working memory among the PILs tested. The implication is that they will be generally difficult to understand and recall. PILs in the other groups should present medium challenges to the average reader.

### 9.2. Comparison of Lexical Density of PILs of the Seven Groups of OTC Medicines

Effort was made to test for statistically significant differences among lexical density scores for the various groups. This was done by means of the inferential statistical procedure known as Analysis of Variance (ANOVA). The data sets fulfilled the assumptions required for a parametric comparison of means (see **Table 4**).

At the $p < 0.05$ level, there were no significant differences in the lexical scores among the seven groups of PILs [$F(6, 60) = 1.859$, $p = 0.103$] (see **Table 4**). This result means that, statistically speaking, each PIL should present the average reader with about the same processing challenge as any of the other PILs tested.

The lexical densities of the PILs tested in this study are generally high. The potential implication of these lapses in communication is that patients may not fully benefit from information regarding their medications that could have been useful.

At the $p < 0.05$ level, there were no statistically significant differences between seven groups of PILs in terms of the mean number of words before main verb in a sentence [$F(6, 60) = 1.836$, $p = 0.107$] (see **Table 5**). However, there was a statistically significant difference between some groups of PILs at the $p < 0.05$ level where number of modifiers per noun phrase was concerned; [$F(6, 60) = 2.697$, $p = 0.022$].

**Table 4.** Analysis of variance of lexical density scores.

| | | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|---|
| lexical density | Between Groups | 906.385 | 6 | 151.064 | 1.859 | 0.103 |
| | Within Groups | 4874.771 | 60 | 81.246 | | |
| | Total | 5781.157 | 66 | | | |

**Table 5.** Comparison of syntactic complexity of 7 groups of PILs.

| | | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|---|
| SYNNLE | Between Groups | 17.578 | 6 | 2.930 | 1.836 | 0.107 |
| | Within Groups | 95.730 | 60 | 1.595 | | |
| | Total | 113.308 | 66 | | | |
| SYNNP | Between Groups | 0.327 | 6 | 0.055 | 2.697 | 0.022 |
| | Within Groups | 1.214 | 60 | 0.020 | | |
| | Total | 1.542 | 66 | | | |

The last two research questions focused on do consumers read PILs of OTC drugs and if they do, do they understand what they read? And whether is there a correlation between the readability of PILs of OTC drugs and consumers response?

The result from the readability and coh-metrix indices indicated that patients of the PILs will face some difficulties when they are using PILs for relevant information. The researcher conducted a mini interview with twenty (20) participants on one to one basis to ascertain whether they read PILs, the level of difficulty the face and the reasons that their reading of PILs. The participants were 7 senior high school students, 9 first degree holders, 2 second degree holders and 1 MBA and 1 post diploma holders. The responses these participants were insightful in that the 12 of the participants read the PILs and the remaining 8 admitted they do not read PILs. The 12 participants who read the PILs submitted that they do that to know information about the drug's dosage, side effect, time to take and indications. Out of the 12 readers of PILs, 7 participants stated difficult terminologies as the cause of their lack of understanding of the PILs. The remaining 5 who understood the PILs were the tertiary participants whose educational level might have influence their comprehension of the text. On the other hand, the participants who did not read the PILs cited time constraints, already knowledge about the drugs and difficulty in understanding the PILs as reasons for their lack of readership of PILs.

For instance, the consumers' responses of complex words and structures were verified through manual analysis of the leaflets. These are examples from the flu and cold leaflets. The words an analgesic (*painkiller*) and antipyretic (*reduces fever*) were used Paracetamol leaflet instead for the simple words in the parenthesis. Also, words such as pseudoephedine—a nasal decongestant which reduces inflammation and blockages of the nasal passages were used instead of simple words. In syntax, sentence structures were relatively long making it difficult for readers to grasp the content easily. To exemplify,

"*Although diclofenc given orally is almost completely absorbed, it is subject to first-pass metabolism so that about 50% of the drug reaches the systemic circulation in the unchanged form.*" (*Emgifenac PIL*)

The sentences were also simple complex ones with relatively high length that

could affect the readability of the leaflet. For instance, one of the sentences is:

"*Cyproheptadine and lysine being an essential and lomoting amino acid helps to promote appetite. Besides helping in the synthesis of collagen tissue*". (Excerpt from Apetamin Leaflet)

It is succinct therefore, patients read PILs and the reasons for their reading of PILs is to know the dosage, side effects, time of taken, expiry dates of drugs and many other relevant information that are captured in PILs. However, their understanding of the PILs is mostly hindered due to the technical terms that are used in the PILs by manufacturers. Moreover, one major cause of the lack of readership by those who did not read the PILs is the lack of understanding of the PILs. In the light of this, the researcher argues that the readability and coh-metrix scores were valid in that readers who had not acquired the required level of education (college level) found the PILs as very difficult to read and understand. Their main reasons for this were the difficult terms used in the PILs which implies that the prediction of the lexical density and grammatical density scores were reflecting the users experience with the PILs text.

Based on the Shannon and Weaver communication model, the researcher can make sense of the result in that the major that hinder effective communication between PILs writers (manufacturers) and the target readers (patients) is semantic noise. The patients did not complain about the materials, font and other mechanical variables, rather an overwhelming majority cited wordiness and one cited lengthiness as the causes of their lack of understanding of the PILs. It therefore implies that, for manufacturers to increase message fidelity of their PILs, there is the need to reconsider the wording and technical terms used in composing PILs so that patients can find them useful for their information needs when they are using drugs. This is much relevant in the Ghanaian setting in a sense that all the interviewees indicated that they do not buy drugs with prescription. This means that their major source of reliable information concerning the drug in order to avoid catastrophic occurrence is the PILs of those drugs. If the PILs are therefore not readable nor lexically and grammatically friendly to patients, the possibility of recording the same casualties that prompted the addition of PILs will be inevitable. Therefore, manufacturers of drugs should give keen attention to the readability of their PILs in order to ensure effective health communication with patients of common ailments studied in this research.

## 10. Conclusions

Health communication is a key for effective health delivery and practice. Therefore, this study has disclosed the readability difficulties associated with patient information leaflets which are vital in guiding patients to make informed decisions regarding self-medicated medicines for treating common illness. The present study found that the leaflets were generally hard to read and understand. The interview with the customers confirmed this trend. There is therefore, the need for composers to revise their writing style by replacing technical words

with plain and simple words and breaking complex syntactical structures into simple readable sentence structures. This will improve health delivery by reducing the communication barrier posed by readability of PILs, and thereby making the PILs useful source of health information for patients.

On this basis, the researchers recommend that writers of the PILs could adopt plain language in order to reduce the lexical and grammatical complexity embedded in the PILs. This will reduce the reading difficulty and makes the PILs readable to vast majority of users of PILs. The researchers recommends that writers of PILs should take advantage of the online readability formulas or Microsoft readability package as tools to predict the reading level of their leaflets for possible revision before circulation of the leaflets to users or patients. The researchers recommend a survey study on the patients readership of PILs and the possible reasons and challenges they encounter. Such a study will help to discover the usefulness of the PILs to patients and the urgency for writer of PILs to consider readability as tool to achieving effective health communication with their users.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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