READABILITY OF THE SOUTH AFRICAN PATIENT PACKAGE INSERT (PPI)

Communitas
ISSN 1023-0556
2009 14: 105 - 124

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ABSTRACT

Although medication is nowadays issued with a package insert containing vital medication information, not everyone reads/understands the medication information contained in the package insert. This has been proven by European and American research, pointing to, amongst other factors, the readability of these documents. Readability difficulty often translates to communication barriers which, in this case, make the accessibility of the health message contained in the PPI difficult. This article investigated the South African situation regarding the readability of PPIs by means of Flesch and Fry readability assessments and a correlation of the results by means of correlation coefficients. The results indicate that for both languages, English and Afrikaans, the texts require at least a tertiary reading ability, which is rare in the broader South African community. This means that the readability of these texts is at present a communication barrier to vital health information a patient needs when taking medication. Although these results only refer to texts variables, one must also realise that reader variables have an important influence on the reading of the material. Yet, by adapting the readability level of these documents, one can already start the process of making the health communication message clearer and more accessible to the South African patient.

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INTRODUCTION

An instruction regarding medication use dates back to the ancient civilisations, around 1500 BC (Mann 1992: 111-115). Nowadays, all medication [scheduled or over-the-counter (OTC)] includes a patient package insert (PPI) with important information directed at the patient taking the medication. Yet written medication information was not, and is not always effectively utilised by patients. From several European studies it is clear that people either do not read and/or understand the PPI (Rudd & Colton 1998: 23; Rudd, Moeykens & Colton 1999: 10). If this is the case in Europe, what is the case in South Africa? If people do not read or understand the medication information, reasons for such conduct should be found, firstly by examining the texts and secondly by investigating human perceptions. This article focuses on an investigation into the PPI text in the South African context.

Concerning the South African situation, during the 19th Century, people suffered a host of epidemics and diseases, such as leprosy, smallpox, cholera, syphilis and typhoid fever and local pharmacists were supposed to "educate an ignorant public in health matters" (Ryan 1986: 2). This was, however, a difficult task due to the isolation of the people living on farms and small villages and a "Huis Apotheek" was often their closest contact with medical care. Although there was an instruction booklet on usage and dosages included in the tin medication container, many people were illiterate or ignorant, and used the medication according to their family tradition, and not according to the included written instructions (Ryan 1986: 2-3). This "booklet" can be seen as the fore-runner of the modern day PPI.

In health communication, like in all other types of communication, the aim is to acquire and process information in order to establish mutual understanding of the message (Thayer 1987: 69). Therefore, the message contained in the PPI should be communicated in such a way that it is easily accessible and comprehensible, if proper use of the medication is to be made. The aim of this document should therefore be to "increase compliance with a medication or treatment plan, better self-manage a condition, provide social support, or provide help with making decisions about health" (Suggs 2006: 62). In order to evaluate the text of patient package inserts for texts variables, as a way to determine the first half of the equation why people do not read or understand the PPIs, readability assessments could be a valid manner of investigation.

READABILITY ASSESSMENTS

Since 1923, many readability assessment formulae have been formulated of which some of the well-known include: Gunning (1945), Dale-Chall (1948), Flesch (1948 and 1950) and Fry (1965) (Tekfi 1987: 268). The Flesch Reading Ease formula, developed in the 1940s, is the best known readability assessment formula still in use today (Smith 2002: 2). As various readability formulae make use of different kinds of counts, they thus yield results that vary (Osborne 2000: 2). Although these formulae vary considerably in mathematical calculations, they all utilise (to a lesser or greater extent) word length and sentence length for readability determination (Ley 1982: 246; Klare

1984: 699-701; Osborne 2000: 2) and therefore indicate text difficulty, based purely on the number and length of words in a sentence.

Normally, word difficulty is expressed by means of the number of syllables, and sentence complexity by the number of words contained in the sentence. These qualifications are, however, not always an accurate indication of text difficulty, as word order and other semantic factors are not taken into consideration. Henry (1989: 98) was of the opinion that the redundancy of a text is also an important variable in the assessment of the readability of the text. According to him, a higher level of redundancy indicates a higher level or readability. The variable used for measuring the redundancy of a text is the "type token ratio", which is calculated as the ratio between the number of "different" words and the total number of words in a passage. The problem with this method is the difficulty to define "different" words, as there might be interpretational differences among researchers. Henry also felt that the degree of concreteness of a message was a contributing factor to the readability thereof (1989: 98).

A readability score, calculated by means of a readability assessment tool, indicates a required school level to read a specific text, but it does not necessarily imply the proficiency of the reader to read at that specific school level (Jackson, Davis, Bairnsfather, George, Crouch & Gault 1991: 1173), the reason being that other factors, such as content, format and organisation of the material also influence the readability of the particular text (Tekfi 1987: 267). Thus, readability formulae do not go without criticism. Agnihotri and Khanna (in Fulcher 1997: 500) showed through their research that conceptual difficulty and textual organisation are very important factors in estimating the accessibility difficulty of texts. Text difficulty also comprises not only sentence-structure complexity, but also ideational complexity (Spadaro, Robinson & Smith (1980: 215-221; Stevens 2000: online), a factor which cannot be calculated by means of the existing readability formulae.

Gilliland (1976: 96) levelled another criticism at readability formulae, namely that these formulae do not take motivational, situational or typographical factors into consideration when determining the readability of a text. Although motivational and situational factors refer more to the reader than to the text, typographical factors are certainly text factors that can have an influence on the readability of a text.

Other defects identified in readability formulae refer to the fact that they do not indicate whether the vocabulary matches the profile of the target audience, whether there is cultural, or any other bias, and whether the design complicates or enhances the readability of the text (Stevens 2000: online). From this can be concluded that a mathematically calculated readability score is merely an indication of the difficulty of a reading passage, where no reader factors or interest in the reading matter are being included in the calculation, yet these formulae remain valuable aids to indicate potential reading difficulty of a text.

Despite the limitations of readability assessment methods, no readability formula has specifically been designed for health and medical information to date. Up to the present, the Flesch Reading Ease formula has been widely used in various types of texts in the English language and its validity has been confirmed by several studies (Smith 2002: 2; Spadaro, Robinson & Smith 1980: 216), also for short texts, such as medication information.

As far as prescription PPIs are concerned, a readability assessment was undertaken on 63 nationally distributed PPIs in America, making use of three assessment methods, namely the Flesch Reading Ease, the Flesch-Kincaid scale and the Gunning Fog Index. The results indicated that the readability of the PPIs was of the 8th to 9th grade difficulty. [The recommended difficulty for such texts in America is comparable to readings texts compiled for readers from the 5th – 7th grade (Basara & Juergens 1994: 49-51)]. Comparable results were obtained in a study on PPIs for oral contraceptives, conducted by Williams-Deane and Potter, in which they investigated legibility (format), the ease with which the texts could be read as well as the ease with which it could be comprehended by means of the Flesch-Kincaid formula. Their results indicated a readability score equal to that of reading matter prepared for learners in the 10th grade, which was considered to be "too difficult" (1992: 114). Concerning the PPIs of OTC medication, studies undertaken by Pyrczak and the Food and Drug Administration (FDA) had lead Pyrczak and Roth (1976), as quoted in Spadaro, Robinson and Smith (1980: 215), to conclude that directions for using non-prescription medication were also too difficult for many people to comprehend. From these results can be concluded that, based on text factors calculated by means of readability formulae, PPI texts in America are "too difficult" for the ordinary patient, and as such could be seen as a barrier in the communication process of medication information with possible negative effects on health outcomes. How does the readability of the South African PPI compare to results obtained from these American investigations?

READABILITY OF THE SOUTH AFRICAN PPI

In this study, the readability of selected PPIs in two languages was determined. Readability formulae designed for English texts are numerous, but there are no suitable readability assessment tools for assessment of the Afrikaans texts of the PPIs. Van Rooyen (1983: 55) developed two formulae specifically for Afrikaans, making use of a five-choice answer strategy, as well as a cloze procedure. These two formulae by Van Rooyen, however, do not allow for educational levels other than standards 6 to 10 (at present grades 8 to 12). Due to this restriction, the formulae by Van Rooyen cannot be utilised for determination of readability of Afrikaans PPIs, as there is an indication (from an initial informal assessment using the Flesch readability formula) that the text difficulty of the English texts are beyond the indicated school years covered by the formulae postulated by Van Rooyen and it is expected that the difficulty level of the Afrikaans texts would meet that of the English texts. The problem was therefore to find an appropriate method that could give comparable outcomes between the two languages (English and Afrikaans).

Sampling

The selection of the PPIs chosen for the readability assessment was done as follows: the chosen PPIs (30 from OTC medication classes and 30 from prescription medication classes) represent most commonly used medication (five drug classes, respectively) according to Roberts (personal communication, 23 July 2002). The medication classes recommended by Roberts were verified with other practising pharmacists. It was decided to randomly select six PPIs from each drug class. It was postulated that six examples from each drug class would give a general idea of the readability within the specific drug class. The random selection of the PPIs from each drug class was executed by another pharmacist at another pharmacy. The drug classes sampled were the following:

TABLE 1: DRUG CLASSES SELECTED FOR READABILITY ASSESSMENT

Prescription medication	**Over-the-counter (OTC) medication**
Analgesics	Analgesics
Blood pressure medication	Decongestion medication
Anti-depressants	Digestive tract medication
Anti-lipidemy medication	Colds and flu medication
Cardiac medication	Tranquilisers

Methodology

It was decided to use the Flesch readability assessment for the English texts of the PPIs, as this has been described in the literature (Basara & Juergens 1994: 49-51; Smith 2002: 2) as a valid method of determining readability of PPIs. In this study, the Flesch readability assessments were done by means of the MS Word computer programme, in all cases using the same starting-point and end-point of the assessments (starting at "Pharmacological action" and ending at "Storage instructions") in order to include the same "sections" in all analyses, with the aim to obtain comparable results within medication classes but also across medication classes.

In research conducted by Berland *et al*. (2001: online), readability assessments were done on health information on the Internet, using the Fry readability assessment for English texts. The researchers wanted to compare the readability of Spanish texts to that of their English equivalents and they used the Fry readability assessment also for the Spanish texts, as the Fry readability assessment makes use of the average number of sentences and syllables per 100 words, and does not include a language-specific constant. This feature makes it useful for readability assessments in languages other than English, for which it was initially developed.

Due to the fact that the Flesch readability assessment makes use of a language-specific constant in its formula, it could not be used for readability assessments of the Afrikaans texts. As there is no applicable method to assess the readability of the Afrikaans PPI texts, it was decided to use the Fry method of calculation, which should yield results comparable to those obtained by the Flesch readability assessment, as both methods use word and sentence lengths. As a means of triangulation to enhance validity and comparability, the Fry assessment was also utilised to assess the readability of the English texts. Where texts were too short for the selection of three passages from which to calculate average values for number of sentences and syllables per 100 words, one or two passages were taken, according to the length of the texts. It also happened that some texts were too short to select one representative passage. In these cases, no calculation of a Fry value was done. The actual word and syllable count of both language texts was done by inserting electronic markers into the texts and then to count them electronically. From these calculations (word and sentence lengths) a value is read from the Fry readability chart, indicating the number of years of schooling necessary to understand the text. The resultant statistics for the Afrikaans assessments were compared to those of the English assessments by means of inspection, followed by correlation coefficients.

The aim of using Fry assessments for the Afrikaans texts as well as the English texts was to be able to construct a means of comparability. If the average number of sentences and syllables per 100 words give an indication of the difficulty of the text, then this method should also be applicable to the Afrikaans texts. It is, however, so that Afrikaans has a tendency to use more multi-syllabic words, while English texts often utilise two separate words to express the corresponding concept. But, at times, Afrikaans also often uses more words to express the same idea as could be expressed in fewer words in English. These linguistic differences could result in great variation in the results obtained. However, if there was to be a constant trend when comparing the values obtained for the two languages, it could be concluded that there is a relative degree of comparison. The resultant scores obtained from the Flesch and the Fry assessments were tabulated and within-category comparisons were done per language group, as well as per drug class for the two languages.

In order to establish correlation coefficients for the two language texts, the following comparisons were made: average sentence length, average number of sentences per 100 words and average number of syllables per 100 words. The correlation calculations were done per medication class, comparing the English texts to the Afrikaans texts. The average sentence length values were used to calculate the Spearman's rank correlation coefficient to establish the possibility of a correlation between the values obtained for the two languages. Since the readability analyses would yield ordinal data, within-category as well as across-category comparisons were undertaken. Comparisons were made between computed scores and distributions for within-drug class data (for the Afrikaans and English copies), calculated by means of the Fry chart for readability. Additionally, correlations between the Afrikaans and English texts per medication class were calculated. Since these data were non-parametric, the Spearman's rank correlation coefficient was used to investigate the possibility of a correlation between the values obtained for the two languages. The formula applied was: $p = 1 - \frac{6 \sum d_i^2}{n(n^2 - 1)}$, where d^2 = the square of the differences in the ranking of the variables and n = number of paired values included in the calculation.

Results

The results obtained for the Flesch readability assessments (English texts) are reflected in a table, followed by readability assessments determined by the Fry method for both language texts. These results are then compared by means of inspection, as well as by comparing average sentence lengths of the two languages and finally correlation coefficients were constructed.

TABLE 2: READABILITY ASSESSMENT OF ENGLISH LANGUAGE PPIs (FLESCH)

Medication class and PPI	Flesch readability assessment	Interpretation of Flesch value	Average per medication class	Range per medication class
Prescription medication:				
Analgesics				
Doxyfene	15.5	Very difficult		
Lentogesic	11.8	Very difficult		
Mypaid	7.5	Very difficult		
Stilpane	18.0	Very difficult		
SynapForte	2.2	Very difficult		
Myprodol	23.1	Very difficult	13.0	2.2 – 23.1
Anti-hypertensives				
Accupril	12.3	Very difficult		
Adco-Bisocor	17.8	Very difficult		
Tarka	11.0	Very difficult		
Adalat	15.8	Very difficult		
Tritace	24.3	Very difficult		
Coversyl Plus	22.8	Very difficult	17.3	11.0 – 24.3
Anti-lipidemy				
Prava	15.3	Very difficult		
Crestor	23.0	Very difficult		
Lescol	16.4	Very difficult		
Lipitor	8.9	Very difficult		
Sandoz Bezafibrate	16.8	Very difficult		
Lovochol	16.7	Very difficult	16.2	8.9 – 23.0

TABLE 2: READABILITY ASSESSMENT OF ENGLISH LANGUAGE PPIs (FLESCH)(CONTINUED)

Medication class and PPI	Flesch readability assessment	Interpretation of Flesch value	Average per medication class	Range per medication class
Prescription medication:				
Cardiac				
Lanoxin	21.3	Very difficult		
Dilatrend	18.7	Very difficult		
Cardarone X	20.2	Very difficult		
Pur-Bloka	21.8	Very difficult		
Concor	18.4	Very difficult		
Zildem	23.8	Very difficult	20.7	18.4 – 23.8
Anti-depressants				
Cymbalta	19.7	Very difficult		
Paxil	23.3	Very difficult		
Efexor	21.9	Very difficult		
Cipralex	17.7	Very difficult		
Cipramil	30.4	Difficult		
Lorien	18.5	Very difficult	21.9	17.7 – 30.4
OTC medication:				
Analgesics				
Stilpane Syrup	18.3	Very difficult		
Lotem Suspension	16.3	Very difficult		
Betapyn	24.7	Very difficult		
Adco-Dol	23.6	Very difficult		
Advil Liqui-Gels	17.7	Very difficult		
Dolorol Forte	27.5	Very difficult	21.4	16.3 – 27.5
Decongestants				
Iliadin Nose Drops	40.1	Difficult		
Demazin	1.4	Very difficult		
Drixine Nasal Drops	22.9	Very difficult		
ENT Nasal Spray	21.3	Very difficult		
Sinumed Tablets	21.0	Very difficult		
Sudafed Tablets	8.0	Very difficult	19.1	1.4 – 40.1

TABLE 2: READABILITY ASSESSMENT OF ENGLISH LANGUAGE PPIs (FLESCH)(CONTINUED)

Medication class and PPI	Flesch readability assessment	Interpretation of Flesch value	Average per medication class	Range per medication class
OTC medication:				
Tranquilisers				
Calmettes Tablets	47.1	Difficult		
Restin Capsules	45.2	Difficult		
Betasleep Capsules	22.1	Very difficult		
Sleepeze-PM Tablets	31.6	Very difficult		
Somnil Tablets	7.0	Very difficult		
Biral	43.3	Difficult	32.7	7.0 – 47.1
Gastro-intestinal				
Immodium Plus	22.0	Very difficult		
Mucaine	19.7	Very difficult		
Valoid	16.8	Very difficult		
Betaperamide Tablets	32.3	Difficult		
Adco-Loperamide Syrup	27.4	Very difficult		
Buscopan Tablets	17.5	Very difficult	22.6	16.8 – 32.3
Colds and flu				
Flusin	11.2	Very difficult		
Colcleer Paediatric Syrup	29.4	Very difficult		
Cepacol Cough Discs	24.9	Very difficult		
Ilvico Tablets	14.3	Very difficult		
Degoran Plus Tablets	29.4	Very difficult		
Corenza-C Effervescent Tablets	34.5	Difficult	24.0	11.2 – 34.5

From the table above it is clear that the average variation in the Flesch readability value (calculated from the respective ranges per medication class) is less among the prescription medication than among the OTC medication (average variation value calculated for prescription medication: 13.3 and for OTC: 25.8). These values indicate that there was less variation in difficulty amongst the prescription medication texts than amongst the texts of the OTC medication. It is, however, clear that all texts were at a difficulty level requiring a person to have training higher than grade 12, as all assessments fell between 1.4 and 47.1 – either in the class "very difficult" or "difficult". [According to the Flesch Reading Ease score, this means that the person reading the text will have to be a college student (in the case of a "difficult" text) and a college graduate (in the case of a "very difficult" classification), respectively (Spadaro, Robinson & Smith (1980: 217)].

The least variation in readability values was seen for the medication class "cardiac" (18.4 – 23.8); indicating the least variation in text difficulty, yet still "very difficult". The greatest variation was noticed for the OTC class "tranquilisers", which yielded a range of 7.0 – 47.1. This is an indication that there is often no standardisation in text difficulty within the same medication class. According to the assessments, only seven (11.7%) of the PPIs (prescription and OTC medication) were considered "difficult", whereas the rest (53; 88.3%) were regarded as "very difficult". Only one PPI in the prescription medication group (3%) was considered to be "difficult", while the rest (29; 97%) were all considered to be "very difficult". The comparative statistics for the OTC medication PPIs were: six (20%) were considered to be "difficult" while 24 (80%) were considered to be "very difficult". From this it can be concluded that the PPIs for OTC medication are slightly more "readable" than those of scheduled medication, yet still difficult.

When comparing the Flesch readability assessments for the two analgesics classes (prescription medication *versus* OTC medication), it is seen that the range for the OTC medication (16.3 – 27.5) was much smaller than that of the prescription medication (2.2 – 23.1) (average difference 11.2 and 20.9, respectively). Although there was greater variability in text difficulty for the prescription medication, the OTC medication yielded texts that were slightly more readable, according to the Flesch calculations. However, the average readability of both these types of medication was considered to be "very difficult".

The following table represents the results obtained from the Fry readability calculations for both English and Afrikaans texts.

TABLE 3: READABILITY ASSESSMENT OF ENGLISH (AND AFRIKAANS) LANGUAGE PPIs (FRY)

Prescription medication				
PPI	**Average number of words per sentence**	**Average number of sentences per 100 words***	**Average number of syllables per 100 words***	**Fry assessment (years of schooling necessary)**
Analgesics				
Doxyfene	21.2 (28.6)	5.3 (3.7)	220.3 (240.5)	> 17 (> 17)
Lentogesic	15.2 (15.9)	4.6 (6.3)	218 (235)	> 17 (> 17)
Mypaid	17.8 (16.8)	5.8 (6.1)	212 (236.3)	> 17 (> 17)
Stilpane	16.0 (15.6)	6.5 (6.7)	216 (247)	> 17 (> 17)
SynapForte	17.8 (16.8)	5.7 (6.1)	221 (246)	> 17 (> 17)
Myprodol	14.0 (16.9)	7.2 (7.0)	206.3 (249.7)	> 17 (> 17)
Anti-hypertensives				
Accupril	22.2 (21.1)	4.6 (4.7)	195.3 (220)	> 17 (> 17)
Adco-Bisocor	19.0 (21.6)	5.9 (5.0)	204.7 (213.3)	> 17 (> 17)
Tarka	18.4 (19.6)	5.5 (5.2)	210.7 (246.7)	> 17 (> 17)
Adalat	18.5 (17.4)	5.7 (6.9)	200.3 (211.3)	> 17 (> 17)
Tritace	22.8 (17.9)	4.4 (5.6)	195 (226.3)	> 17 (> 17)
Coversyl Plus	20.2 (18.7)	5.1 (5.5)	185.7 (191.7)	> 17 (> 17)
Anti-lipidemy				
Prava	17.6 (18.8)	5.7 (5.3)	193.3 (209.7)	> 17 (> 17)
Crestor	21.5 (22.1)	5.2 (4.8)	207 (226)	> 17 (> 17)
Lescol	21.2 (18.1)	4.8 (5.7)	203.7 (202.3)	> 17 (> 17)
Lipitor	20.4 (25.0)	5.2 (4.1)	205.7 (231.7)	> 17 (> 17)
Sandoz Bezafibrate	15.6 (16.1)	6.5 (6.2)	199 (225.7)	> 17 (> 17)
Lovochol	23.8 (22.8)	4.4 (4.6)	185 (219.3)	> 17 (> 17)
Cardiac				
Lanoxin	22.7 (22.3)	4.9 (4.9)	213.7 (222.3)	> 17 (> 17)
Dilatrend	19.3 (22.5)	5.3 (4.6)	191.3 (212.7)	> 17 (> 17)
Cardarone X	24.2 (20.7)	4.3 (5.1)	197.3 (206.7)	> 17 (> 17)
Pur-Bloka	19.7 (20.4)	5.6 (5.0)	208.3 (227.3)	> 17 (> 17)
Concor	21.3 (18.1)	4.9 (5.6)	182 (207)	> 17 (> 17)
Zildem	16.7 (15.8)	6.1 (6.5)	211.7 (230.3)	> 17 (> 17)

* Used to determine the Fry readability assessment.

TABLE 3: READABILITY ASSESSMENT OF ENGLISH (AND AFRIKAANS) LANGUAGE PPIs (FRY) (CONTINUED)

Prescription medication				
PPI	**Average number of words per sentence**	**Average number of sentences per 100 words***	**Average number of syllables per 100 words***	**Fry assessment (years of schooling necessary)**
Anti-depressants				
Cymbalta	15.9 (16.8)	6.5 (6.1)	196 (217)	> 17 (> 17)
Paxil	22.3 (18.3)	4.5 (5.4)	191.7 (199.3)	> 17 (> 17)
Efexor	22.9 (24.2)	4.8 (5.2)	186.7 (210)	> 17 (> 17)
Cipralex	16.7 (20.8)	6.0 (4.9)	184 (230.3)	> 17 (> 17)
Cipramil	12.2 (16.1)	8.5 (6.3)	216.7 (218.3)	> 17 (> 17)
Lorien	19.8 (23.4)	5.7 (4.9)	196.7 (211.3)	> 17 (> 17)
OTC Medication				
Analgesics				
Stilpane Syrup	16.8 (21.5)	6.1 (4.9)	211.3 (228)	> 17 (> 17)
Lotem Suspension	16.3 (14.1)	6.2 (7.2)	200.3 (240)	> 17 (> 17)
Betapyn	13.1 (12.7)	7.6 (7.9)	190.7 (212.7)	> 17 (> 17)
Adco-Dol	17.6 (16.5)	5.8 (6.3)	203.3 (238)	> 17 (> 17)
Advil Liqui-Gels	18.0 (15.9)	5.8 (6.6)	226.3 (232.7)	> 17 (> 17)
Dolorol Forte	17.6 (16.8)	6.0 (6.3)	186.3 (222.7)	> 17 (> 17)
Decongestants				
Iliadin Nose Drops	13.0 (15.4)	7.7 (6.2)	187 (223)	> 17 (> 17)
Demazin	21.1 (19.3)	4.8 (5.3)	218 (248)	> 17 (> 17)
Drixine Nasal Drops	12.4 (11.7)	7.3 (8.4)	208.3 (193)	> 17 (> 17)
ENT Nasal Spray	15.3 (13.3)	6.6 (7.8)	204 (138)	> 17 (6)
Sinumed Tablets	17.2 (15.9)	5.8 (6.3)	217 (239)	> 17 (> 17)
Sudafed Tablets	15.2 (14.5)	6.6 (6.9)	213 (220)	> 17 (> 17)

* Used to determine the Fry readability assessment.

TABLE 3: READABILITY ASSESSMENT OF ENGLISH (AND AFRIKAANS) LANGUAGE PPIs (FRY) (CONTINUED)

OTC Medication				
PPI	**Average number of words per sentence**	**Average number of sentences per 100 words***	**Average number of syllables per 100 words***	**Fry assessment (years of schooling necessary)**
Tranquilisers				
Calmettes Tablets	Too short for analysis			
Restin Capsules	Too short for analysis			
Betasleep Capsules	Too short for analysis			
Sleepeze-PM Tablets	16.7 (17.2)	6.0 (5.8)	188 (201)	> 17 (> 17)
Somnil Tablets	19.6 (16.6)	5.2 (6.1)	221 (221.5)	> 17 (> 17)
Biral	Too short for analysis			
Gastro-intestinal				
Immodium Plus	18.7 (17.9)	5.5 (5.7)	190 (206.7)	> 17 (> 17)
Mucaine	22.6 (20.8)	4.5 (4.9)	201.5 (244)	> 17 (> 17)
Valoid	17.2 (16.9)	6.1 (6.7)	218.7 (241.5)	> 17 (> 17)
Betaperamide Tablets	20.4 (19.6)	4.9 (5.1)	151 (184)	10 (> 17)
Adco-Loperamide Syrup	13.5 (14.3)	7.4 (7.0)	175 (203)	15 (> 17)
Buscopan Tablets	Too short for analysis			
Colds and flu				
Flusin	16.6 (15.3)	6.5 (7.0)	208 (246.7)	> 17 (> 17)
Colcleer Paediatric Syrup	Too short for analysis			
Cepacol Cough Discs	21.7 (21.7)	4.6 (4.6)	195 (209)	> 17 (> 17)
Ilvico Tablets	17.5 (21.3)	5.7 (4.7)	221 (235)	> 17 (> 17)
Degoran Plus Tablets	16.4 (17.2)	6.1 (5.8)	195 (229)	> 17 (> 17)
Corenza-C Effervescent Tablets	18.5 (20.0)	5.4 (5.0)	193 (220)	> 17 (> 17)

* Used to determine the Fry readability assessment.

According to the Fry determinations for the Afrikaans texts, all PPIs fell within the category "grade > 17" (more than 17 years of education), except that of the PPI for ENT nasal spray which required grade 6 (six years of education). For the English texts, the texts of Betaperamide tablets and Adco-Loperamide syrup required training of less than 17 years, while the Afrikaans texts still indicated a level higher than 17 years of education.

The results obtained for the Fry calculation for Afrikaans texts correspond largely to those of the English texts, although the syllable count was in general higher for the Afrikaans texts, most probably due to way texts are formulated in Afrikaans.

When comparing the different medication classes, with reference to the average sentence lengths, as a feature of text style, the following results were obtained:

TABLE 4: COMPARISON OF AVERAGE SENTENCE LENGTHS OF PPIs

Prescription Medication		**OTC Medication**	
Average number of words per sentence (Afrikaans values in brackets)		Average number of words per sentence (Afrikaans values in brackets)	
Analgesics	17.0 (18.4)	**Analgesics**	16.6 (16.3)
Anti-hypertensives	20.2 (19.4)	**Decongestants**	15.7 (15.0)
Anti-lipidemy	20.0 (20.5)	**Tranquilisers**	18.2 (16.9)
Cardiac	20.7 (20.0)	**Gastro-intestinal**	18.5 (17.9)
Anti-depressants	18.3 (19.9)	**Colds and flu**	18.1 (19.1)

From Table 4 it is clear that there was little variation in the average sentence lengths among medication classes and also between Afrikaans and English texts. The range for prescription medication (English texts) was 17.0 – 20.7 words per sentence, whereas the average for the Afrikaans texts varied between 18.4 and 20.5 words per sentence. The average number of words per sentence for the English prescription medication was 19.2 words while the Afrikaans texts yielded an average of 19.6 words per sentence. This relatively small variation could indicate that the messages in these texts are probably formulated in a similar manner. However, higher average values for sentence lengths of the Afrikaans texts were seen for the following prescription medication classes: analgesics, anti-lipidemy and anti-depressants as compared to anti-hypertensives and cardiac medication.

For OTC medication, the range of average number of words per sentence was 15.7 – 18.5 and 15.0 – 19.1, for English and Afrikaans, respectively. The average number of words per sentence for the English OTC medication texts was 15.4 words. The comparative value for the Afrikaans texts was 17.0 words. This could possibly also be contributed to the Afrikaans language structure. However, less variation between the average sentence lengths was seen in the OTC medication classes, where all values, but that of colds and flu, were lower for Afrikaans texts than for the English texts. This could indicate that there is less variation between the two languages in the way the message in the OTC text is constructed.

When comparing the two analgesics classes (prescription and OTC medication), it is clear that the average sentence length values were lower for the OTC medication than the prescription medication, for both the languages. This can be interpreted as the OTC texts of both languages being "easier" than those of the prescription analgesics, due to the average shorter sentence lengths. Yet, the difference in average sentence lengths between the prescription and OTC analgesics was fairly small (a difference of 0.4 words for English texts and 2.1 words for Afrikaans texts). These results suggest the possibility of a comparative trend between the two languages across medication classification (prescription *versus* OTC medication). However, it must be kept in mind that this method of calculation (Fry readability assessment), does not allow for complexity of words. In general, the values obtained for the OTC medication were lower than those of the prescription medication, indicating shorter sentences, and by implication, higher readability. Fairly comparative average sentence length values were obtained for the two languages across all medication classes which were further investigated by means of correlation coefficients.

In order to calculate correlation coefficients six values per medication class of the prescription medication were used, except in the case of the OTC medication, where three medication classes yielded less than six values from which to calculate the correlation coefficients. These OTC medication classes were: "tranquilisers" (two) and "gastro-intestinal" and "colds and flu" (both five values). The low number of values, especially in the case of "tranquilisers", rendered the correlation coefficients obtained for this medication class not reliable. The following table reflects the results of these calculations.

TABLE 5: CORRELATION COEFFICIENTS PER MEDICATION CLASS

Prescription Medication				OTC Medication			
	Average sentence length	**Average number of sentences per 100 words**	**Average number of syllables per 100 words**		**Average sentence length**	**Average number of sentences per 100 words**	**Average number of syllables per 100 words**
Analgesics	0.3714	0.6357	-0.3143	**Analgesics**	0.4714	0.5286	0.4286
Anti-hypertensives	-0.0286	-0.0286	0.4857	**Decongestants**	0.6000	0.4143	0.6571
Anti-lipidemy	0.5429	0.5000	0.6000	**Tranquilisers**	-1.0000	-1.0000	1.0000
Cardiac	0.3143	0.1857	0.6571	**Gastro-intestinal**	1.0000	1.0000	0.9000
Anti-depressants	0.8286	0.4714	0.0286	**Colds and flu**	0.8000	0.9000	0.7250

When comparing the three correlation coefficients per medication class, as reflected in the table above, it is seen that there was greater consistency for the OTC medication classes than for the prescription medication, excluding the medication class "tranquilisers". (Only two values were available for this medication class, rendering the correlation coefficients not reliable.) However, great variation was seen in the correlation coefficients calculated for the prescription medication. From this can be concluded that, provided there are enough values from which to calculate the correlation coefficient, any of the three criteria can be used to compare Afrikaans texts to English texts in the OTC medication class. In the case of prescription medication, there was a slight degree of consistency between the correlation coefficients calculated from the average sentence length and the average number of sentences per 100 words. The calculations for prescription medication, based on the average number of syllables per 100 words, gave values that were inconsistent with the other two methods of comparing the two language texts.

From these calculations it became apparent that, although there was a correlation between the two language texts – however weak – especially in the case of prescription medication, the strongest correlation was found amongst the OTC medication classes. These results also suggest that, if a readability assessment considers an English PPI text to be "difficult", it could be assumed that the same would most probably be true for the corresponding Afrikaans text. However, no absolute comparability was established.

DISCUSSION AND CONCLUSION

From the calculations done it was clear that both the Flesch readability assessment and the Fry assessment indicated that most of the English PPI texts were considered to be "very difficult", or in a few cases "difficult". In general, a person would need schooling of more than 12 years to understand the texts. The Afrikaans texts rendered comparative values to the English texts for the Fry assessment method, re-affirming the degree of difficulty attributed to these texts.

From the Spearman's rank correlation coefficients, calculated for the English and Afrikaans texts for prescription medication, it could be seen that, in general, there was a correlation, however weak. All the correlation coefficients for the OTC medication were positive values (excluding the class "tranquilisers" in which case only two values were available), leading to the conclusion that there was a stronger direct correlation for readability between the Afrikaans texts and the English texts for the OTC medication classes than for those of the prescription medication. It was clear from these calculations that presumptions could be made concerning the difficulty of Afrikaans texts, based on the readability assessments of the English versions of the particular text, provided that there were enough values from which to calculate a correlation coefficient, and provided that the correlation coefficient indicated a direct relationship between the two texts.

As the readability of a medication information text is the first step to comprehension of the information, is speaks for itself that reading difficulty could deter a patient from reading it and by implication could result in negative health decisions and/or drug compliance. Readability is therefore very important to ensure the success of a PPI, and Amery and Van Winkel (1995: 54) offered the following advice to improve the readability of PPIs: sentences should be short, uncluttered and to the point with simple rather than complex sentence construction and the texts should be personalised through the use of personal pronouns. Additionally, Fitzmaurice and Adams (2000: 260) suggested specifically that scientific jargon should be avoided, as these terminologies often become communication barriers. Riche, Reid, Robinson and Kardash (1991: 288-289) found that technical words, the use of passive voice and rare phraseology were confusing and negatively impacted on the readability of material. They also found that readers rather preferred more meaningful words than less meaningful words, seen from the perspective of the patient. These findings correspond with those of Renkema who devised a model (the CCC model for correspondence, consistency and correctness of a scientific texts), in which it is indicated that the wording should be appropriate, there should be unity of style and correct syntax and choice of words (Janssen & Neutelings 2001: 40-44), all adding positively towards the readability of the texts.

Although shortening of sentences and making use of "easier" words may result in lower readability scores (and therefore, theoretically, easier to read passages), this would not imply that the material is indeed more comprehensible, or more interesting to the reader. According to Osborne, the following should be borne in mind when writing texts that will be more readable: focus on the information the reader "needs to know", organising the material in ways that make sense to the implied reader and assembling the material in such a way that it is inviting to read (2000: 2). Stevens (2000: online) suggested the following measures to enhance readability of texts: the use of simple language, omission of unnecessary words, unambiguous sentence structures and an orderly organisation of the information.

Additionally, readability formulae make use of the assumption that the relationship between increasing word and sentence difficulty, and the readability of the material, would be a linear relationship. McLaughlin (in Gilliland 1976: 97) postulated that this relationship was curvilinear, which implies that at the lower end of reading ability, an increase in text difficulty would necessitate a considerable increase in reading skill in order to read the more difficult text. Therefore, if a Flesch readability assessment indicates a value of 50 or less, the text would be even more "difficult" for the ordinary patient. (For the Flesch determination of prescription medication, these values all fell within the interval 1.4 – 47.1 and thus clearly too difficult for the ordinary patient). The implication is that the lower literate is more adversely affected by a difficult text than someone who has better literacy, or has had more schooling. To prove how complex the readability matter is, in research done by Jackson *et al.*, a computer programme ("Grammatik software package") was used to calculate readability based on the following variables: the number of words, the number of sentences, the average sentence length and the number of syllables in each word and then calculated the Fog-Index and the Flesch-Kincaid Index from these data. This calculation was then used to determine the grade-level of difficulty.

The research findings of these researchers indicated that in patient populations, the last grade completed at school did not correlate with the patient's actual reading ability (1991: 1173), the more reason that the readability of the present PPIs should receive the necessary attention in order to make them more accessible to the ordinary person.

In the end, the readability of material is reflected in the comprehension of the communication message and deals, however, with both semantic and the human factors. Yet, the readability value could be an indication of the degree of difficulty that the reader will encounter in reading the text. However, research by McAdams, as quoted in Fulcher (1997: 500), indicated that reader interest in the reading topic is more important than the sentence lengths. Regarding the readability of a text, Stevens (2000: online) concluded: “Both semantic and syntactic elements are surface-level features of the text, and do not take into account the nature of the topic or the characteristics of the readers”. But the readability is definitely the staring point for accessing the message and comprehending it.

Concerning the South African PPI, in April 2005 the South African Medicines Control Council (MCC) published a set of guidelines which should be followed for PPIs. The opening statement indicates the aim of the PPI, as seen by the MCC: “The intention of this guideline is to enhance consistency in the content of package inserts and to ensure that the information included under the different headings is clear and sufficient for the proper use of the medicine, while keeping in line with Regulation 9 (1) of Act 101, 1965, as amended” (MCC 2005: online). It can however be asked whether the patient, given the difficult readability values of the South African PPIs, will judge the medication information as “clear and sufficient for the proper use of the medicine”.

It must further be remembered that in the South African health communication context, the real health education challenge lies in the lower socio-economic and low literate groups. This means that it will be these people who are more seriously affected by difficult readability than the higher groupings. And this is not even taking reader variables, such as interest, language ability and skills and previous exposure to similar texts into consideration. The Drug Information Association (DIA), at a meeting in 1999 in Gauteng, expressed its concern about medication information as follows: “Although it is generally accepted that a medicine comprises a drug and drug information, limited provision is made to ensure adequacy of patient information. High levels of illiteracy, confusing package inserts and labels, and limited availability of patient information leaflets and other appropriate patient information are widespread problems in Africa” (Barnes, Gunston, Edwards & Mehta 2001: online). It is thus clear that if the PPI intends to communicate a readable (and comprehensible) message, the formulation of the message should be addressed. Texts should be tested for readability in order to ensure that the text variables contribute to the clear communication of the medication message and a concerted effort is necessary to accommodate people with lower educational and literacy levels. It is still another matter to accommodate reader variables in this equation.

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