Investigating the Syntactic Structures of Patient Information Leaflets

Hadil Kanaan Ibrahim[1*], *Hairuzila* BT Idrus[2]

[1] Iraqi Ministry of Education, Baghdad, Iraq

[2] Social Science & Humanities Department, Universiti Teknologi PETRONAS, Malaysia

Abstract. The majority of the Malaysian people consider the Patient Information Leaflets (PILs) of their medications difficult to read and understand because of their linguistic complexity. Clear and comprehensive PILs will help the users/readers gain the benefits of these PILs. Poor and complex PILs will cause lack of adherence to the medications being used. The current study aims first, to investigate the use of command, passive voice and negation currently used in the Malaysian PILs, their frequent occurrence and their effect on readers' comprehension. A total of 10 leaflets of the most common disease in Malaysia, which is diabetes, were tested. The analysis was done first, by applying statistical descriptive analysis to show the frequency and percentage of each syntactic structures. Second, a comprehension questionnaire was carried out with 210 participants to evaluate the reading comprehension of the users/readers based on two texts. The original text which consists of sentences taken from the PILs and the revised text, which consists of the revised sentences of the original ones. Based on the results, command scored the highest mean value than passive and negation. Additionally, the results of conducting the comprehension questionnaire showed that most of the participants chose the revised text for command, passive and negation, respectively. These results revealed that most of the participants consider the revised text easier to read and understand than the original text. In conclusion, the linguistic complexity of the PILs will prevent users/readers from utilizing the benefits of the medical information provided by these PILs.

Keywords— Patient Information Leaflet; syntactic structures; Malaysian PILs

I. INTRODUCTION

Patient Information Leaflets (PILs) are small pieces of health documents containing medical information inserted inside each medication package. They provide the patients with information about the medicine being used, for example, how to use the drug, its side-effects, dosage, and storage. Patients always expect to get information that helps them to make informed decisions about their health. They need to have, good quality information about drugs, particularly over-the-counter drugs which are not prescribed by physicians. Dressler and Eckkrammer [1] describe PILs as texts containing many structures and convey several functions besides their social function to guide the patients to manage their disease and self-therapy.

Though the significant value of PILs is well accepted, still there are some doubts concerning its quality regarding their content, language, template and design [2-6]. Previous studies have shown that the text of the PILs is poorly understood by patients [7-10]. This is in contrast to the aim of the European Parliament legislations. These legislations (they are universal legislations and all the countries followed them and Malaysia is one of these countries) have made it obligatory that each PIL must contain easy to read and understand medical information as mentioned in Article 63(2) of the EU Directive 2001/83/EC [11]. Hence, PILs are called an obligatory genre, which means heavily, legally regulated genres [12, 13] governed by legislative regulations [14]. Malaysia is one of the Asian countries that follow the EU Parliament Directives and the EU Commission "Guideline on the readability, 1998".

*Corresponding Author: hadilahmed2004@yahoo.com

Whether a text is complex or not depends on its grammatical structures. Some texts are either formal i.e. containing many grammatical structures such as the language used by experts or informal such as our everyday language used among friends and families. Consequently, the language of PILs is considered formal and complex since it uses many grammatical structures and complicated medical expressions [15]. According to Blanck & Nyblom, (2012), patients still find PILs difficult to read and understand and many studies have shown that most of the PILs are still linguistically complex. The reason for this complexity is that the text of these PILs is complex and this is against the function and purpose of this genre [16]. On the other hand, people diagnosed with chronic diseases such as diabetes, need clear PILs with good medical information to help them in their long-term therapy and health care management [17, 18].

Studies on improving the language and information employed in PILs started more than a decade ago. Nevertheless, PILs are still considered complex in their language, structure and the way they are written [19]. Therefore, more research should be carried out to investigate in details the PILs linguistically, syntactically and semantically because large number of people using these PILs still face difficulty in understanding them and this misunderstanding can cause serious health problems that can lead to death.

II. LITERATURE REVIEW

Patient information leaflets are medical documents found inside each medicine package to provide the patients with the needed health information. According to Article 11 of Directive 2001/83/EC [11], the content of these leaflets should be clear, understandable and easy to read in order to help people to act appropriately. The amended Directive 2004/27/EC [11] insisted on having a readability and comprehension test of PILs, this was in 2004. Then the "Guideline on the label and package leaflet of medicinal products for human use" was published by the European Commission in 1998. The guideline states how to produce well-designed and understandable leaflets explicitly [20]. It also shows how the content, design and layout of the PILs should be. In 2005, the readability user test was introduced by the European Commission to evaluate the readability and usability of the PILs for the patients. Since then it has become obligatory to test the readability and usability of the PILs of any new medical product [21].

The European Medicine Agency has redesigned the PILs templates to make these PILs linguistically precise, consistent and accurate [22]. Despite all the efforts made to improve the readability and the comprehensibility of the PILs, patients are still faced with long texts written in small font size [16] and difficult to understand medical expressions [23].

So far, a notable number of studies have emphasized on improving the readability, organization, and layout of the PILs [24] but little literature is published on the use of the syntactic structures in the PILs and their impact on text comprehensibility. Moreover, the EU Commission "Guideline on Readability", (1998) has pointed out clearly every point related to ensure having good PILs, but when it comes to the syntax of the PILs they only state that "sentences should be formulated in an active and direct style". Therefore, more research must be done to investigate the use of the syntactic structures in the PILs and their effects on the complexity of these PILs. This study aimed to investigate the frequency occurrence of some grammatical structures (command, passive voice and negation), their use in the PILs and their effects on user's/reader's comprehension.

III. SYNTACTIC STRUCTURES

People always criticize the language of medicine as being difficult to read and understand. One of the reasons behind this difficulty is the complex nature of medicine. The medical language uses many difficult medical expressions which belong to a highly specialized language; the language of medicine. PILs, as demanded by the European Council and the Medicines and Healthcare Products Regulatory Agency (MHRA), as a form of medical document containing medical information meant for the users must be written in a way that helps the reader to understand the information presented and hence, helping the patient to use the medication correctly and safely. However, these PILs till to date have problems concerning their linguistic complexity and readability. One of these difficulties is attributed to the structure of PILs which use many complex grammatical structures and long complicated sentences [15]. This makes the users/readers spend more time to look at the whole sentence structure to make it coherent and clear. Though there were few studies published concerning the effect of using the grammatical structures (command, passive and negation) on the reader's comprehension of the information presented in the PILs, nevertheless, these studies assured that such grammatical structures effect on PILs' comprehension [25-27]. Hence, this study discusses these syntactic structures first, to investigate their frequency of occurrence and their use by applying descriptive statistical analysis technique. Second, to investigate their effects on users/reader's comprehension by conducting a comprehension questionnaire with 210 participants.

IV. AIM OF STUDY

The objective of this study is to examine the use of command, passive voice and negation, their frequent occurrence in the PILs and their influence on users'/readers' difficulty in understanding these PILs.

V. METHODS

The National Pharmaceutical Regulatory Agency (NPRA), a department in the Malaysian Health Ministry, has published on their online website many versions of PILs of almost all the medications currently used in pharmacies including the PILs of the imported medications which were written for native speakers of English while the English language is considered as a second language in Malaysia. These published PILs were written according to the regulations of good and easy to read PILs in order to make it easy for the Malaysian people to read and understand these PILs. The present study will investigate the linguistic complexity of the Malaysian leaflets published by the NPRA.

According to the World Health Organization (WHO) [28], diabetes disease is the most common disease in Malaysia. Therefore, ten diabetes leaflets were analyzed in this study. The researcher investigated the use of command, passive voice and negation, their occurrence in the ten leaflets and their impact on text comprehensibility. The analysis process of these structures based on three sources. The first is Trimble's (1985) division of commands into 'direct instructions 'and 'indirect instructions' and Sless and Shrensky's usability guidelines (2006) for analyzing the commands. The Second is the EU Commission "Guideline on the readability, (2009) for analyzing the passive and the third is de Vogelaer [29] and Burgers, et al. [27] for analyzing the negation.

The quantitative method is utilized here to analyze the text of the selected leaflets statistically. The statistical descriptive analysis is used to show the frequencies and percentages of these three syntactic structures in the selected leaflets. In the current study, the most influential variables were two. First, the independent variable which is the complexity of the three syntactic structures (command, passive and negation). Second, the dependent variable of this study is user's/readers' comprehension of the PILs' text. Users/readers' comprehension is tested through conducting a questionnaire to measure reading comprehension.

VI. DATA COLLECTION

SAMPLING

This is an explanatory study to investigate 10 diabetes PILs which were written and published by the National Pharmaceutical Regulatory Agency in the Malaysian Health Ministry. A purposive sampling was used in the current study and the ten diabetes leaflets were selected from the online database of the National Pharmaceutical Regulatory Agency of Malaysia. The selected PILs were the best-selling medications in pharmacies and most used by diabetes patients as they were frequently prescribed by doctors.

PARTICIPANTS

In total, 210 respondents recruited among patients in a hospital, general public and from online Yahoo groups. The aim is to examine whether the original text of the Malaysian PILs or their revised text, done by the researcher, is easier to read and understand. The participants had to be 18 years old or older since the researcher is only interested in the opinion of the adult people and they should have good literacy skills because they should be able to read and understand English in order to read and understand the PILs.

VII. QUESTIONNAIRE

In order to investigate the impact of using the three syntactic structures (command, passive and negation) on the text comprehensibility of the Malaysian PILs, a questionnaire was developed to test reading comprehension of 210 participants. Command, passive and negation were the features to be tested in this questionnaire. The questionnaire contains two columns, the first column consists of 15 original sentences taken from the original text of the leaflets and the second column consists of 15 revised sentences of the same original ones. The 15 sentences used in the original and revised texts are categorized into three sections, each one consists of 5 sentences. The first 5 are command sentences, the second 5 are passive sentences and the last 5 are negation sentences. Two professionals, a linguist and a senior clinical pharmacist evaluated and supported the items of the questionnaire. The researcher has revised the original sentences of the command according to the guideline of usability of Sless and Shrensky,

(2006) while the original sentences of passive were revised according to the EU Commission, "Guideline on the readability", (2009). Finally, the sentences of negation were revised according to Burgers et al., (2015). Participants were presented with the questionnaire and were asked to read the original sentence first then the revised one and then tick the easier sentence to read and understand from their perspective.

VIII. DATA ANALYSIS

The analysis process began by counting manually the occurrence of command, passive and negation in the sentences of the ten diabetes leaflets. For the reliability of the manual analysis results of the 10 PILs, the researcher analyzed the first 5 PILs, then the same process was repeated by another person for the same 5 PILs so that both results were independently recorded. It was found that there were no differences between both analyses for the 5 leaflets, so, the researcher finished the analysis of the remaining 5 leaflets without a need for a double check by the other. Although, grammar-checking programs can make the process of calculating the frequency of these syntactic structures easier, but, the results are not always accurate.

Then, second, the data were analyzed statistically using IBM SPSS Statistics version 22. Descriptive statistical analysis was carried out to express the results as frequencies, percentages, means and standard deviation. According to the literature (Sless and Shrensky, (2006); Burgers et al., (2015) and Amdur, (2010) these three structures when used so frequently and inappropriately in the PILs, this may increase the linguistic complexity of the PILs' text and influences on users' comprehension.

IX. RESULTS

The results from the statistical analysis of the ten leaflets revealed that the mean and average percentage was found equal to 36.20 (3.26 %), 21.40 (1.95 %) and 26.70 (2.41 %) for command, passive and negation, respectively. The standard deviation of command was 9.34, passive was 11.60, and negation was 6.70. The maximum value for the command was 51, passive was 39 and finally, negation was 35. While the minimum values were 23, 9 and 18 for command, passive and negation, respectively as shown in Table 1. Table 2 shows the distribution of frequency of occurrence of each syntactic structure within each leaflet.

TABLE I. DESCRIPTIVE STATISICS OF DIABETES LEAFLETS

Structure	No	Mean	Std.dev.	Max	Min
Command	10	36.20	11.60	51	23
Passive	10	21.40	9.34	39	9
Negation	10	26.70	6.70	35	18

TABLE II. Distribution of frequency of leaflets

Name of the leaflet	Passive	Command	Negation
Clamide	9	23	18
Diabitol	23	23	18
Diamicron	39	37	35
Glimaryl	10	23	19
Galvus® Met	32	49	34
Glucophage Xr	25	35	30
Januvia®	21	28	27
Kombiglyze® Xr	17	51	32
Onglyza	15	43	31
Glimicron 80 Mg	23	50	23

The findings showed that command recorded the highest frequency of occurrence in the ten leaflets, more than passive and negation. This higher frequency of command is due to the fact that PILs are instructional documents containing health information. Their language uses many commands or imperatives [30]. These commands are orders, requests, warnings, and information about the medication [31, 32]. Because PILs aim "at making the receiver act, think or behave in a certain way" [33] good communication happens when "orders and commands acquire a cooperative value" [34].

According to Trimble [32], there are two kinds of commands or "instructions": 'direct instructions' which use the regular command form of the verb, and 'indirect instructions' which may use modal verbs, the passive mode or mix both. Consequently, both kinds were found in the selected leaflets, direct instructions and indirect ones, for example:

Follow doctor's advice. (Diabitol Tablet)

You should therefore always carry some form of sugar with you. (Diamicron 30 mg Tablet)

Things you must do. (Clamide Tablet; Diabitol Tablet & Glimary1 Tablet 2 mg)

Overall, the average percentage of the direct instructions in the ten leaflets was found as 61 % and the average percentage of indirect instructions was found as 39 %. This result correlates with what Sless and Shrensky have emphasized on, that instructions should be written "as commands, with the action word (keep, tell, do not take it, etc.) first" (Sless & Shrensky, 2006, p. 38). This is because research revealed that "readers assume that the most important matter will come first in a sentence or a paragraph and often only read the first part" (Sless & Shrensky, 2006, p. 34).

The 'direct instructions' were expressed by a verb followed by a direct object. The commands were used in two cases: prescriptions and proscriptions, for example:

Do not take a double dose to make up for a missed one. (Diabitol)

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives. (Glimicron)

If you forget to take your dose, take it as soon as you remember. (Clamide)

Do not stop taking the medicine unless advised by your doctor. (Januvia)

On the other hand, the 'indirect instructions' were expressed by using modals, semi-modals and modals written in passive constructions [32]. According to Dodds, (2012), this is done intentionally to make the sentence ambiguous in order "to impede understanding on the part of the receiver" (2012, p. 58). Then, the marketing holders will not be responsible for how the users will act, for example:

Your doctor should ensure that the following tests are performed. (Galvus® Met)

*If you have diabetes you should have your blood or urine tested for sugar regularly. (*Glucophage XR).

Moreover, the modal 'must' have been used three times only within each leaflet, this is because authorized pharmaceutical companies avoid using strong commands that imply strong meaning of obligation to force consumers to do actions since this can lead to less adherence to the PILs [35]. For example,

When you must not use it. (Galvus Met)

Things you must not do. (KOMBIGLYZE XR)

Based on the above analysis, the syntactic structure, the command, seems to be used appropriately in the current PILs, nevertheless, its use was not clear enough or direct. Moreover, no one PIL adhered totally to Sless and Shrensky [31] guideline recommendations. This is due to some reasons:

(1) Using indirect instructions with modals, semi-modals or modals with passive constructions can cause the action of the command to be lost [31], for example,

Medicines should not be disposed of via wastewater or household waste. (Diabitol)

You should observe the treatment plan prescribed by doctor to achieve proper blood sugar levels. (Diamicron).

KOMBIGLYZE XR should not be used to treat type 1 diabetes. (KOMBIGLYZE XR)

(2) Commands are placed wrongly. This means using more than one command in one sentence. This causes the action of the command to be compressed with other commands and the "action gets lost in the sentence" [31]. For example,

If you forget to take Galvus Met, take it as soon as you remember and take your next dose at its usual time. (Galvus Met)

Concerning the impact of command on text comprehension, the results of the questionnaire showed that 27 (12.86 %) of the participants have chosen the original command sentences while 183 (87.14 %) of them chose the revised ones. See the examples below:

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. (original)

- **Skip the dose you missed**.
- **Take your next dose on time.** (revised)

If you or someone else has taken too much gliclazide, contact your doctor or pharmacist immediately. (original)

- **Contact your doctor immediately in case of overdose.** (revised)

Most of the participants appreciated the clear and easy way of writing the revised command sentences. They were satisfied with using bold type and bullets in listing some instructions. Moreover, they said that it was easy for them to read and find the information quickly. Also, they commented positively about using direct instruction at the beginning of the sentence. These results correlate with Sless and Shrensky's recommendations on how to write good instructional PILs.

The second most occurring syntactic structure in these leaflets was a negation. The mean and average percentage of negation was 26.70 (2.41 %). This means that negation is less used in the selected leaflets and this is preferable. As a matter of fact, negative words or sentences are frequently occurring in PILs, for example, '*unable, not able, never, only'* because as a medical document, PILs are meant for the safety of patients and there should be information that prohibits patients from doing things that might cause them health problems [36]. According to de Vogelaer [29], there are two main kinds of negation: the morphological and the sentential negation. The morphological negation contains words ending with prefixes that imply negation, such as *well-unwell* or *accurate-inaccurate.* While the sentential negation is divided into two kinds: the explicit and the implicit negations. Explicit negations contain words such as, *no* or *not* while implicit negation contains either a fusion of '*not*' with another word such as, *not ever- never, not anybody-nobody* or having words that convey negation partially such as, *only, scarcely, few, hardly..etc.*

The results showed that there were 66 (24 %) occurrences of morphological negations in the ten leaflets. While the occurrences of the sentential negation were as follows: 210 (78 %) occurrences of the explicit negation and 7 (2 %) of implicit negations. For example,

*If the patient is **un**conscious immediately inform a doctor and call the emergency service.* (Diamicron)

*If you have **un**explained stomach problems, tell your healthcare provider.* (KOMBIGLYZE XR)

*Do **not** take a double dose to make up for a forgotten dose.* (GLUCOPHAGE XR)

***No** specific instructions.* (Glimaryl)

***Never** give it to anyone else.* (JANUVIA)

The above results showed that the sentential negation was more used in the leaflets under study, especially the explicit negation, than the morphological. Moreover, all the leaflets performed quite well concerning using less negation forms in the side effect section, which is recommended in the previous studies [27]. The reason is that consumers always have difficulties in understanding the risk information presented in the side effect section [23, 36] and using negation will increase the complexity of the PILs. The reason is that the side effects section in any PILs tends to be long with most information in it and patients may miss some important information if many prohibited sentences were used. The exaggeration on risk information and using many negation forms will lead to frightening the user who may change his/her mind about taking the medicine at the end.

Furthermore, the results of the questionnaire revealed that 51 (24.29 %) of the participants have chosen the original texts on negation while 159 (75.71 %) of them chose the revised texts on negation. See the examples below:

*Children: COVAPRIL tablets are **not** for use in children.* (original)

Doctors always recommend COVAPRIL tablets for adults. (revised)

*Type 2 diabetes develops if the body does **not** make enough insulin or if the insulin that the body makes does not work as well as it should.* (original)

Type 2 diabetes develops if the body produces little insulin that fails to work properly. (revised)

Almost all the participants indicated that the revised texts were more clear, direct and easy to read and understand than the original ones. Moreover, the revised texts were more specific in giving direct information without using negation forms which, as mentioned earlier, can exaggerate the risk information and this will frighten the reader/user. This correlates with many studies conducted within the field of communication science which concluded that using negation in medical writings can cause misunderstanding on the part of the reader since negation carries extra meaning [37]. Based on that, using negative forms in a text affects the text comprehensibility because they are considered indirect and difficult to understand, unlike the affirmative forms [38, 39]. Moreover,

using negation in medical texts influences on the "actual and subjective comprehension" [27]. Actual comprehension measures how people actually understand and comprehend the information while subjective comprehension measures the complexity and readability of the information. Studies had shown that negation does influence people's understanding of the PILs and makes these leaflets more complicated. This complexity of the text will lead to less appreciation from patients towards the information of these PILs.

The third most occurring syntactic structure in these leaflets was passive. The mean and average percentage of passive was 21.4 (1.95 %). The analysis showed that only two types of passive forms were used in the leaflets under study: the simple present passive tense (Subj. + to + be + pp.) and the infinitive passive tense (Subj. + modals + be + pp.). There were 96 (0.87 %) occurrences of the simple present passive tense and 39 (0.35 %) occurrences of the infinitive passive tense, for example,

You are advised to take it as long as your doctor tells you to. (Clamide)

It is recommended that you take your tablets either with or just after food. (Galvus Met)

Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM. (Januvia)

ONGLYZA may be passed in your milk to your baby. (Onglyza)

High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary. (KOMBIGLYZE XR)

Passive is used to **depersonalize** the medical text by omitting the doer of the action and focusing more on the action itself [40]. In other words, it is more important to emphasize the effects and the results of an action rather than who is doing that action. This omitting of the doer of the action is because these medical texts are written by specialists who are more concerned with describing what and how things happened and what are the results. Moreover, it is obvious that the implicit agent is the physicians, specialists, and researchers. So, there is no need to mention them because it would be a redundant thing to do so. According to the EU Commission " Guideline on readability" 1998, sentences in the PILs should be written in an active style [20]. On the other hand, Sless and Shrensky advised PILs' writers to "avoid the passive voice" because it is not obvious who is doing the action and using long sentences with passive constructions cause the action to be lost (Sless & Shrensky, 2006, p. 43)

Furthermore, there is an argument led by Sheen [41] that the medical language should avoid using the passive and if necessary reduce it. The reason is that using the passive form makes the text less clear, less powerful and more ambiguous. The other argument stated that medical writings should use the passive form to be more objective and scientific, this was supported by Scarpa [42]. According to the second argument, using the passive form in medical texts gives formality and objectivity to these texts and this is the primary purpose of medical writings as scientific texts.

Since there is no much literature or studies stating the appropriate amount or the percentage of passive voice used in writing medical texts, this study has depended on the results of Amdur, Kirwan & Morris, (2010). According to their recommendations, the medical text writers should make a passive voice frequency of ≤ 10 % as a requirement for publishing all types of medical works. As long as the current study is concerned, the percentage of the passive voice frequency in the ten leaflets was 1.95 %. This value is considered less than the recommended value suggested by Amdur, Kirwan & Morris (2010). Then, the ten leaflets under study are considered acceptable in their use of passive voice.

Now, concerning the results of the questionnaire, these results showed that 42 (20 %) of the participants have chosen the original passive sentences while, 168 (80 %) of them chose the revised ones and in their comments they stated that the revised sentences were very clear, easy to read and understand because they were written in the active form.

My results relate to the existing literature on the syntactic structures used in medical writings such as, command, passive, and negation which show how these structures can influence the comprehension and understanding of the PILs. Despite the guidelines provided by the EU and their aim to make PILs easier to read and understood, PILs are still currently criticize for being difficult to read and understand by people. This misunderstanding is due to the fact that there are some linguistics areas related to comprehension not covered yet such as the use of the syntactic structures. This study has shown that the command, passive and negation are different syntactic forms repeatedly used within the PILs and are not mentioned in the EU guidelines and laws. Such structures and other grammatical features need to be investigated thoroughly, and PILs designers need to consider these structures when they start to write and design their PILs to make these necessary medical documents more beneficial for patients who use them as their primary source of health information.

X. Discussion and Conclusion

Patients always want to get good-quality health information which helps them to make correct health decisions, in particular, over-the-counter drugs which are not prescribed by physicians and to use their medication safely and appropriately. My results tie with the argument that more attention should be paid to the aspect of comprehensibility of PILs because they have many syntactic structures to convey valuable medical information which can affect the understandability of such information by people. Thus, for those experts or professionals who are engaged in the process of writing these medical leaflets, it is important for them to reconsider the way they write these leaflets with and to pay attention to the negative impact of using such structures on the perception of the patients. Because, for example, using negative structures will reduce the PILs appreciation by patients who use these leaflets as the primary source of health information available for them. Thus, when patients consider a leaflet complex and challenging to understand, they become less concerned with doing what the leaflets required them to do. So, this must be taken into consideration when designing the PILs.

As far as using the commands in the PILs, it is preferrable to use a numbered list of instructions as authorized by Sless and Shrensky, [31]. Besides, commands or imperatives should be written in bold font throughout the whole leaflet to attract the reader's attention and make the information clearer. While "[t] he only case when instructions must be in 'plain text' and not in bold is in the numbered list of instructions" [31]. This is because "If you want consumers to carry out two or more separate actions, give them two or more separate instructions [and] try [not] to compress more than one action into a single sentence" [31]. They also emphasized on using direct commands like (keep, store, take, tell, etc.). Since previous studies showed that "readers assume that the most important matter will come first in a sentence or paragraph and often only read the first part" [31], they suggested that we should reduce or avoid using the passive form to carry out commands because it is not obvious who supposed to do a particular action. Sometimes the action itself is misleading and lost in the sentence, and this produces long sentences. They focused on using "positive instructions" more than negative ones and using negative " only when you want consumers to avoid specific actions" [31].

According to Burgers et al., (2015) the use of negation influences the understanding of the medical information presented in the PILs. This influence is because negation introduces an opposite meaning. Although the EU has published many guidelines about how to make PILs easier to read and understand, nevertheless, the users of these PILs still face difficulty in perceiving them. This study showed that despite all these guidelines, there are some aspects influencing patient's comprehension and have not been discussed in detail before. Such aspects are the syntactic structures used in PILs. So, for future studies, it is recommended that more research should be carried out on the syntactic structures of the PILs, and the designers of the PILs should pay more attention to these structures to get a better understanding, useful and safe use of these important medical documents.

The other structure highlighted here is the use of passive voice forms. Passive forms are frequently used within the PILs. This is due to the professional writers of these PILs who prefer to use the depersonalization manner in writing the medical texts. Apparently, the reason is, they are more engaged with the results and outcomes of the action rather than declaring who is the doer of the action. Myers [43] said that sometimes scientific writers tend to avoid using the passive form because they considered passive as impersonal and lack politeness and using them implies a universal truth-value. While the reason why the passive form is frequently used in medical writings is that, using passive reflects objectivity which is one of the main aims of scientific writings. According to Halliday [44] the frequent use of passive voice forms, as an "impersonal style", in medical writings situated the results of the action in its thematic place rather than the doer of the action. Based on the results, it is clear enough that using the syntactic structures (command, negation and passive) according to the recommendations and guidelines of the EU Commission and Sless and Shrensky [31] can make the text of the PILs easier to read and understand by the readers. Difficult texts influence on people's adherence to read the whole PIL and considered it as a source of medical information to be used in the future. The analysis revealed that using the three syntactic structures, command, negation and passive was appropriate within the text of the Malaysian PILs. But conducting the reading comprehension questionnaire of the revised and original texts revealed that the PILs under investigation needs to be promoted and reconsidered again, especially in the area of using the above syntactic structures.

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