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Original Article

Evaluation of summary of product characteristics and patient information leaflet of the best-selling drugs in Turkey in terms of readability

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ABSTRACT

Background and Aims: Readability can be defined as the easiness or difficulty of texts to be understood by readers. In our study, it was aimed to evaluate the patient information leaflet and the summary of product characteristics in terms of readability in Turkish.
Methods: Our study is a cross-sectional study. For our study, the best-selling drugs included in the "Turkish Pharmaceutical Market Monitoring Report-8, 2020 Market Status in Terms of Sales Volume and Value" prepared by the Turkish Medicines and Medical Devices Agency in 2021, were evaluated by using Turkish readability formulas (Ateşman and Bezirci-Yılmaz).
Results: 138 patient information leaflet and summary of product characteristics of a total of 69 products were evaluated. It has been determined that an average of at least undergraduate education is required for the readability of the texts. The patient information leaflets are significantly shorter than the summary of product characteristics (p=0.000). However, in terms of readability, it was easier in Ateşman calculation and more difficult in Bezirci-Yılmaz calculation (p=0.007 and p=0.000, respectively).
Conclusion: It has been seen that patient information leaflets are not easy to read texts prepared for patients. While preparing the texts to be read by the patients, the texts should be easily understandable and should be read and understood by people of all education levels.
Keywords: Health literacy, comprehension, Pharmaceutical Preparations, Prospectus

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INTRODUCTION

In today's health system, the expectation of service providers from service users is increasing(Nielsen-Bohlman, Panzer, & Kindig, 2004). The patriarchal doctor-patient relationship has been replaced by a relationship in which individuals understand, decide, and apply the information given in writing or verbally, and as a result, they take their own health responsibilities. An effective health literacy is needed for all these roles to be fulfilled effectively (Ilbars & Özkan, 2020; Nielsen-Bohlman et al., 2004).

Health literacy is a new concept in which health and literacy come together. The World Health Organization examines health literacy in three dimensions: functional, interactive, and critical literacy(Kanj & Mitic, 2009). Functional health literacy refers to the ability of individuals to understand and act in accordance with written texts such as drug prospectuses, informed consent, and informational texts given by health personnel (Erdoğan & Araman, 2017; Williams, Baker, Parker, & Nurss, 1998). While low functional literacy directly affects the health of the individual, it also increases the unnecessary use of health facilities (Baker, Parker, Williams, & Clark, 1998).

With the Regulation on Licensing of Medicinal Products for Human Use published in our country in 2005, summary of product characteristics (SmPC) and patient information leaflet (PIL) were introduced for newly licensed products (Sağlık Bakanlığı, 2005). Accordingly, SmPC will be prepared only to inform health professionals and to use the medicinal product effectively, which is not included in the product box. There will also be PIL in the product box prepared in accordance with the SmPC to inform the patients (Sağlık Bakanlığı, 2005). Making this distinction, in a way, shows that patients are expected to read the relevant product information and take responsibility for their own health.

Readability can be defined as the texts' being easy or difficult to be understood by the reader and it can be measured objectively. In the readability calculation, parameters such as the number of words in the sentence, the average number of syllables of words, and the number of multi-syllable words are included. Although there are more than 40 readability formulas that come from the past and are still used, most of these formulas have been prepared in accordance with the English language structure (Philipson, Doyle, Gabram, Nightingale, & Philipson, 1995). In Turkey, certain readability formulas such as Ateşman and Bezirci-Yılmaz formulas, which are suitable for Turkish language structure, are used (Ateşman, 1997; Bezirci & Yilmaz, 2010).

In our study, it was aimed to evaluate PIL prepared for patients and SmPC prepared for health professionals in terms of readability in Turkish using mathematical formulas and to determine which education level in patients it appeals to.

MATERIAL AND METHODS

For our study, the "Turkish Pharmaceutical Market Monitoring Report-8, 2020 Market Status in terms of Sales Volume and Value" report prepared by the Turkish Medicines and Medical Devices Agency (Türkiye Ilaç ve Tibbi Cihaz Kurumu; TITCK) in 2021 was taken as a basis. According to the sales volumes of 2020 in this report, the top 20 drugs, which are the most sold in total, the most sold without a prescription, covered by Social Security Institution (Sosyal Güvenlik Kurumu, SGK) and private insurance, were evaluated (a total of 80 drugs) (Table 1). (Sağlık Bakanlığı, 2021).

The current SmPC and PIL information of the drugs in this list was obtained from the official website of TITCK (https://www.titck.gov.tr/kubkt). If there is more than one SmPC or PIL information for a drug, the most up-to-date one was included in the evaluation. Although it is included in the report, "fortini multifibre strawberry flavored, 200 ml", which does not have SmPC- PIL information on TITCK's website, could not be evaluated.

With 20 drugs in each group, a total of 80 drugs from 4 groups were evaluated, but in the case of a drug that has the same active ingredients and the product names and is included twice in the list due to the number of tablets in it, only one of these drugs has been evaluated (such as Parol 500 mg tablet, 20 tablets and Parol 500 mg tablet, 30 tablets). Therefore, 10 drugs listed twice and 1 drug without SmPC-PIL information were excluded, and a total of 69 drugs were evaluated.

Ateşman and Bezirci-Yılmaz readability formulas were used in the readability calculation. Ateşman readability formula was developed in 1997 as an adaptation of Flesch readability formula into Turkish (Ateşman, 1997). It is calculated as: Readability score = 198.825 – 40.175 x word length (total syllables / total words) – 2.610 x sentence length (total words / total sentences). An increase in the score indicates an increase in readability. The difficulty levels and the level of education required by the scores are shown in Table 2.

The Bezirci-Yılmaz readability formula was developed in 2010 in accordance with the Turkish language structure, without being an adaptation of a foreign formula (Bezirci & Yilmaz, 2010). According to the results obtained, the level of education required by the text is determined (Table 3). The formula is calculated as follows: Readability score= √OKS x ((H3 x 0.84) + (H4x1.5) + (H5x3.5) + (H6x26.25)) OKS: average word count; H3: mean number of 3-syllable words; H4: mean number of 4-syllable words; H5: mean number of 5-syllable words; H6: the average number of words with 6 or more syllables.

In order not to affect the calculation, the product names and registration information in the SmPC-PIL were not taken into consideration. A software developed by Bezirci-Yılmaz (BET-okunabilirlik.exe) was used to evaluate the remaining parts (Bezirci & Yilmaz, 2010). The fractional results obtained for the education level were rounded to the nearest integer.

The "Word Frequency Dictionary of Written Turkish" published by the Turkish Language Association in 2018 was used to look at the number of difficult words in theSmPC and PILs, and the words that are not among the basic 3000 words here are defined as "difficult words".

SPSS 18 package program was used in the analysis of the data. Whether the data were normally distributed or not was evalu-

Table 1. The top 20 drugs, which are the most sold in total, the most sold without a prescription, covered by Social Security Institution (Sosyal Güvenlik Kurumu, SGK) and private insurance (Sağlık Bakanlığı, 2021).

TOP 20 DRUGS SOLD TOTAL	TOP 20 DRUGS SOLD WITHOUT PRESCRIPTION*
PAROL 500 MG TABLET, 20 TB	PAROL 500 MG TABLET, 20 TB
CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB	DOLOREX DRAJE, 20 DRAJE
ARVELES 25 MG FILM TABLET, 20 TB	ARVELES 25 MG FILM TABLET, 20 TB
DOLOREX DRAJE, 20 DRAJE	CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB
BELOC ZOK CONTROLLED RELEASE FILM TABLET 50 MG 20 TB	DEVIT-3 IM/ORAL AMP.
NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TABLET	MAJEZIK 100 MG 15 FILM TABLET
PAROL 500 MG TABLET (30 TABLET)	PAROL 500 MG TABLET (30 TABLET)
ECOPIRIN 100 MG ENTERIC COATED TABLET, 30 TABLET	ASPIRIN TABLET 20X0.5G (20 TABLET)
LANSOR MICROPELLET CAPSULE 30 MG 28 CAP	VERMIDONE TABLET (30 TABLET)
MAJEZIK 100 MG 15 FILM TABLET	NOVALGIN 500 MG TABLET, 20 TB
TRAVAZOL LEATHER CREAM (15 G)	DEVIT-3 ORAL DROPS 50.000 IU (15 ML)
DEVIT-3 IM/ORAL AMP.	NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TB
FORTINI MULTIFIBER STRAWBERRY FLAVORED, 200 ML	CALPOL SUSPENSION
DEVIT-3 ORAL DROPS 50.000 IU (15 ML)	A-FERIN FORT FILM TABLET 30 TB
INFATRINI 200 ML.	NUROFEN COLD & FLU 200MG/30MG FILM
GLIFOR 1000 MG FILM TABLET (100 TABLET)	COATED TABLET (24 TABLET)
PLAVIX 75 MG 28 FILM TABLET	TRAVAZOL LEATHER CREAM (15 G)
AUGMENTIN BID 1000 MG FILM TABLET, 14 TABLET	ECOPIREN 100 MG ENTERIC COATED TABLET, 30 TB
NOOTROPIL FILM TABLET 800 MG 30 TB	VENTOLIN INHALER 200 DOSES
VENTOLIN INHALER 200 DOSES	APRANAX FORT FILM COATED TABLET, 20 TABLET
	THERAFLU FORTE FILM TABLET (20 TB)

TOP 20 DRUGS PAID BY SGK	TOP 20 DRUGS PAID BY SPECIAL INSURANCES
CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB	CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB
PAROL 500 MG TABLET, 20 TB	AUGMENTIN BID 1000 MG FILM TABLET, 10 FILM TB
ARVELES 25 MG FILM TABLET, 20 TB	PAROL 500 MG TABLET, 20 TB
BELOC ZOK CONTROLLED RELEASE FILM TABLET 50 MG 20 TB	TRANKO-BUSKAS 10 + 10 MG COATED TABLET (20)
DOLOREX DRAJE, 20 DRAJE	ARVELES 25 MG FILM TABLET, 20 TB
NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TB	RITALIN 10 MG TABLET (30 TB)
ECOPIREN 100 MG ENTERIC COATED TABLET, 30 TABLET	BELOC ZOK CONTROLLED RELEASE FILM TABLET 50 MG 20 TB
LANSOR MICROPELLET CAPSULE 30 MG 28 CAP	AUGMENTIN BID 1000 MG FILM TABLET, 14 TABLET
PAROL 500 MG TABLET (30 TABLET)	DEVIT-3 ORAL DROPS 50.000 IU (15 ML)
FORTINI MULTIFIBER STRAWBERRY FLAVORED, 200 ML	DEVIT-3 IM/ORAL AMP.
INFATRINI 200 ML.	GERALGINE-K TABLET 20 TB
TRAVAZOL LEATHER CREAM (15 G)	DOLOREX DRAJE, 20 DRAJE
GLIFOR 1000 MG FILM TABLET (100 TABLET)	NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TB
PEDIASURE PLUS FIBER STRAWBERRY FLAVORED 220 ML	LYRICA 300 MG CAPSULES (56 CAPSULES)
NOOTROPIL FILM TABLET 800 MG 30 TB	NEURONTIN 800 MG NOTCHED FILM COATED TABLET (50 TB)
PLAVIX 75 MG 28 FILM TABLET	MAJEZIK 100 MG 15 FILM TABLET
PEDIASURE PLUS FIBER BANANA FLAVORED 220 ML	XANAX 1MG 50 TABLET
VASOXEN 5 MG TABLET, 28 TB	BELOC ZOK CONTROLLED RELEASE FILM TABLET 25 MG 20 TB
FORTINI MULTI FIBER BANANA FLAVORED 200 ML	LANSOR MICROPELLET CAPSULE 30 MG 28 CAP
FORTINI MULTI FIBER CHOCOLATE FLAVORED 200 ML	PLAVIX 75 MG 28 FILM TABLET

* It refers to the first 20 drugs obtained from pharmacies by patients without SGK payment and prescription.

ated with the Kolmogrov - Smirnov test. Student's t test, Mann Whitney U test, two-way ANOVA and descriptive statistics were performed. Normally distributed data are given mean. ± Std Deviation, non-normally distributed data are given as mean (min, max). The statistical significance value was taken as $p<0.05$.

Ethics committee approval was obtained for the study from Erzincan Binali Yıldırım University Clinical Research Ethics Committee with the date 28.04.2022 and decision number 15.

RESULTS

138 SmPC-PIL of 69 products in total were evaluated. The mean readability score was calculated as 43.8±6.2 for Ateşman and 15±2.4 for Bezirci-Yılmaz, respectively; It corresponds to 13th-15th grade level education requirement for Ateşman and undergraduate level education requirement for Bezirci-Yılmaz.

The number of words, sentences, words, difficult words, syllables and polysyllabic words of SPC-IFUs are given in the t Table

Table 2. Difficulty and education levels corresponding to the score obtained with the Ateşman readability formula(Ateşman, 1997).

Score	Difficulty level	Education level
90-100	Very easy	Can be read by anyone with a 4th grade and below.
80-89	Easy	Can be read by anyone with a 5th or 6th grade education
70-79		Can be read by anyone with a 7th or 8th grade education
60-69	Medium difficulty	Can be read by anyone with a 9th or 10th grade education
50-59		Can be read by anyone with an 11th or 12th grade education
40-49	Hard	Can be read by anyone with a 13th or 15th grade education.
30-39		Can be read by anyone with a bachelor's degree.
1-29	Very hard	Can be read by anyone with a postgraduate degree.

Table 3. Education level corresponding to the score obtained with the Bezirci–Yılmaz readability formula (Bezirci & Yilmaz, 2010).

Grade	Education level
1st - 8th	Primary education
9th – 12th	Secondary education
12th – 16th	Undergraduate
16th+	Academic level education

SmPc and PIL scores are given in the Table 6 according to the most sold in total, the most sold without a prescription, covered by SGK and private insurance ,and no significant difference was found between the groups in terms of both Ateşman scores and Bezirci-Yılmaz scores (respectively p=0.815, p=0.760).

DISCUSSION

The World Health Organization (WHO) defines health literacy as "an individual's ability to access, understand and use health information for the protection and maintenance of health"(Kanj & Mitic, 2009). The concept of "readability", which can be measured objectively and indicates the level of easy readability of the read text by the reader, is directly related to health literacy. In our study, it was aimed to investigate the readability level of SmPC and PILs .

Studies have shown that most of the patients forgot or misunderstood the information they received from the physician or other health personnel(Calkins et al., 1997; Makaryus & Friedman, 2005). In a study, it was found that patients forgot at least half of what the physician said about 5 minutes after leaving the

Table 4. Comparison of SmPC* and PILs in terms of number of sentences, words, syllables and polysyllabic words.**

	SmPC / PIL	Mean	Min	max	p
Number of sentences	SmPC	339.03	164	571	0.000
	PIL	178.07	98	284	
Word count	SmPC	3363.61	1813	6822	0.000
	PIL	2260.54	1389	3358	
Difficult word count	SmPC	3526.46	1775	6558	0.000
	PIL	2205.29	1363	3273	
Number of syllables	SmPC	1074.,62	5194	18860	0.000
	PIL	6347.48	3485	9312	
Number of polysyllabic words	SmPC	1291.83	607	2240	0.000
	PIL	721.99	332	1049	

*SmPC: Summary of Product Characteristics; ** PIL: Patient Information Leaflet

4, and in all groups,PILs are statistically shorter than SmPCs (p=0.000) (Table 4).

When we look at the difficult word ratio in SmPC-PIL it was seen that 97.09 ±1.12 of SmPC and 97.50±1.65 of PIL consisted of difficult words. Although this rate was higher in PILs the difference was not found to be significant (p=0.083).

Considering the readability scores of the SmPC and PIL a significant difference was found between both Ateşman and Bezirci-Yılmaz scores (p=0.007, p=0.000, respectively) (Table 5).

Table 5. Comparison of the readability scores of SmPC* - PILs.

		n	Mean	Std. Deviation	Corresponding education level	p
Ateşman	SmPC	69	42.43	5.00	13-15th grade	0.007
	PIL	69	45.25	6.95	13-15th grade	
Bezirci-Yılmaz	SmPC	69	14.57	1.67	Undergraduate	0.000
	PIL	69	15.51	2.93	Undergraduate	

* SmPC: Summary of Product Characteristics; **PIL: Patient Information Leaflet

Table 6. Comparison of readability scores of best selling drug groups.

		Ateşman			Bezirci-Yılmaz	
		n	Mean	Std. Error	Mean	Std. Error
Most sold in total	SmPC	17	43.61	5.23	14.30	1.76
	PIL	17	45.37	6.52	15.26	3.00
	Total	34	44.49	5.89	14.78	2.47
*Most sold without a prescription**	SmPC	20	41.41	5.62	14.50	1.81
	PIL	20	45.96	7.45	15.36	2.84
	Total	40	43.68	6.90	14.93	2.39
Covered by SGK	SmPC	13	41.61	3.90	15.10	1.15
	PIL	13	44.34	7.62	15.75	3.39
	Total	26	42.98	5.88	15.42	2.50
Covered by private insurance	SmPC	19	43.00	4.82	14.53	1.78
	PIL	19	45.02	7.08	15.74	2.82
	Total	38	44.01	6.06	15,13	2.40

* It refers to the first 20 drugs obtained from pharmacies by patients without SGK payment and prescription.

exam room(Kitching, 1990). In another study conducted with 623 patients, only 31% of the patients stated that they were adequately informed by the physician about the side effects of the medication (Enlund, Vainio, Wallenius, & Poston, 1991).

Today, due to the increasing need for health care and increasing workload, especially with the Covid-19 pandemic, physicians cannot spare enough time for their patients and provide the necessary information (Auwal, Tanimu, Samira, & Hadiza, 2022; Desideri et al., 2021). For this reason, the importance of the instructions for use in medicine boxes and especially prepared for the patients to read is increasing. Patients are expected to take more responsibility for their own health problems.

In our study, it was seen that an average of 13th-15th grade is required for Ateşman, and undergraduate education is required for Bezirci-Yılmaz in order to understand the texts. According to the data of the Turkish Statistical Institute for the year 2020, 63% of the citizens in Turkey have received secondary education and below, and are considered within the scope of the population with low education (Türkiye İstatistik Kurumu, 2020). The rate of getting education at the level of 13th grade or higher is only 16% (Türkiye İstatistik Kurumu, 2020). According to these statistics, SmPC and PILs have been prepared at a level that cannot be understood by a large part of the society.

Although there were close values in the calculations, it was seen that the readability was slightly higher in the Ateşman calculation. As mentioned before, the Ateşman readability formula is not a formula prepared entirely in accordance with the Turkish language structure, but is an adaptation of the Flesch readability formula to Turkish (Ateşman, 1997). Although Turkish and English are two completely different languages in terms of structure,the quantities considered in the readability formulas are almost the same. Since Turkish has an additive language structure, it can be said that it is a more difficult language than English in terms of language learning (Solak & Bayar, 2015). For this reason, the Bezirci-Yılmaz readability formula, which is more suitable for the Turkish language structure, was developed by Bezirci and Yılmaz in 2010 (Bezirci & Yilmaz, 2010). Although this formula seems to be more suitable for the Turkish language structure, both formulas are frequently used in the literature. Therefore, both formulas were used in our study.

Considering the average number of sentences, words and syllables, PILs are significantly shorter than SmPCs. However, this brevity was not reflected in the texts at the same level as readability. Although PILs were found to be more readable in terms of Ateşman score, in the Bezirci-Yılmaz calculation prepared in accordance with the Turkish language structure, PILs were

found to be less readable. In addition, the words that are considered as "difficult words" because they are not among the basic 3000 words in Turkish were used at a higher rate in PILs, but at a rate of over 97% in both SmPC and PILs. From this point of view, it has been seen that PILs are short forms of SmPCs rather than texts that are easier to read and prepared for patients.

There was no difference in readability between the drug groups that are most sold, most sold without a prescription, and most sold covered by SGK and private insurance. Here, it would be appropriate to regulate the PILs of the most sold without prescription drugs and to prepare more legible texts.

SmPC and PILs should have certain standarts.The current standards in Turkey were published in the period of 2007-2008 and were prepared according to the 2005 European Union guidelines (Türkiye İlaç ve Tıbbi Cihaz Kurumu, 2007, 2008). In these guides, the order of the subtitles to be used in SmPC and PIL, the font and size to be used, even the paper type etc. are clearly stated. On the other hand, suggestions were made as "short sentences should be used", but features such as what is meant by shortness, number of syllables, number of words were not specified. We think that it would be appropriate to evaluate SmPC and PILs with readability formulas accepted by the literature before they are used, and to set certain standards in this respect by taking into account the education level of the society.

It can be said that readability is a new concept in the medical literatüre (Ay & Duranoğlu, 2022). No other study that has previously evaluated the readability of SmPC and PILs has been found in the literature. However, one of the biggest limitation in our study is to evaluate only the readability, not the intelligibility of the text. Therefore, there is a need for further studies, such as the Patient Education Materials Evaluation Tool, in which the understanding levels of patients are also evaluated (Vishnevetsky, Walters, & Tan, 2018). Nevertheless, our study is one of the first studies in this field and is a valuable study in this respect.

Using a plain and simple language, preparing texts consisting of words with few syllables and short sentences are essential in improving readability. While preparing the texts that the patients will read, the texts should be prepared at a level that everyone can read and understand. Those who prepared these texts should never make the mistake of only shortening the texts prepared for healthcare professionals. Such an approach would be more appropriate in the form of today's changing health service delivery.

CONCLUSION

The patient information leaflets (PILs) are at the same level as the texts prepared for health professionals in terms of readability.

While preparing PILs instead of using a simple and more understandable language, the original texts were shortened.

In today's health system, where the patient is expected to take more responsibility for their own health, the texts prepared for patients (PILs) should be prepared at a level that can be read by all segments.

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Informed Consent: Written consent was obtained from the participants.

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