



ISSN 2395-650X

International Journal of
Life Sciences Biotechnology Pharma Sciences

IJLBPS



www.ijlbps.org

E-mail: editorijlbps@gmail.com editor@ijlbps.org

Analyzing The Most Popular Turkish Medications' Patient Information Leaflets And Summaries Of Product Features For Readability

G.Thanusha, G.Suresh, L.Sunil, Bishwajit Patowary

Abstract:

Context and Objectives: The term "readability" refers to the degree to which a book is easy or difficult for readers to grasp. The purpose of our research was to assess the Turkish readability of a patient information leaflet and a product features summary. **Methods:** A cross-sectional study is what we've done here. In our study, we used the Turkish readability formulas developed by Ateşman and Bezirci-Yılmaz to assess the top-selling medications from the "Turkish Pharmaceutical Market Monitoring Report-8, 2020 Market Status in Terms of Sales Volume and Value" published by the Turkish Medicines and Medical Devices Agency in 2021. **End result:** A total of 69 goods had their 138 patient information leaflets and product characteristic summaries reviewed. In order to understand the texts, one needs a bachelor's degree or above, on average. With a p-value of 0.000, the product characteristics summary is much longer than the patient information leaflets. Ateşman calculation was simpler in terms of readability, but Bezirci-Yılmaz calculation was more difficult ($p=0.007$ and $p=0.000$, respectively). The results show that patient information booklets are not well-written, straightforward texts. All individuals, regardless of their level of education, should be able to read and comprehend the materials that will be given to the patients. Preparation for Pharmaceutical Use, Health Literacy, and Prospectus

Keywords: Health literacy, comprehension, Pharmaceutical Preparations, Prospectus

INTRODUCTION

According to Nielsen-Bohlman, Panzer, and Kin dig (2004), patients and their families have higher expectations of healthcare professionals in the modern system. The traditional doctor-patient dynamic has given way to one in which patients actively participate in their own healthcare by reading, processing, and acting upon written or spoken instructions. To properly carry out all of these responsibilities, a high level of health literacy is required (Ilbars & Özkan, 2020; Nielsen-Bohlman et al., 2004). The novel idea of health literacy combines the formerly separate concepts of health and literacy. Functional, interactive, and critical literacy are the three aspects of health literacy that the World Health Organization considers

(Kanj & Mitic, 2009). The capacity for patients to comprehend and adhere to written materials including medication brochures, informed consent forms, and informative texts provided by healthcare professionals is known as functional health literacy (Erdoğan & Araman, 2017; Williams, Baker, Parker, & Nurss, 1998). Both the individual's health and the frequency with which they visit the hospital are negatively impacted by poor functional literacy (Baker, Parker, Williams, & Clark, 1998). The introduction of the summary of product characteristics (SmPC) and patient information leaflet (PIL) for newly licensed drugs was

SAMSKRUTI COLLEGE

prompted by the 2005 publication of our country's Regulation on Licensing of Medicinal drugs for Human Use (Sağlık Bakanlığı, 2005). Thus, the only thing contained in the product package that SmPC will be ready for is to educate health experts on how to utilize the medicinal product properly. In order to warn patients, the product box will also have PIL that is developed according to the SmPC (Sağlık Bakanlığı, 2005). Differentiating in this manner implies that patients are required to read the pertinent product information and be accountable for their own well-being. It is possible to objectively quantify readability, which is defined as the degree to which writings are simple or difficult to understand by the reader. When determining readability, factors including sentence length, average word syllable count, and frequency of multi-syllable words are taken into account. According to Philipson, Doyle, Gabram, Nightingale, and Philipson (1995), the majority of the forty readability formulae that have been developed so far have been designed to be compatible with the English language. Specifically, readability formulae developed for the Turkish language structure, including the Ateşman and Bezirci-Yılmaz formulas, are used in Turkey (Ateşman, 1997; Bezirci & Yılmaz, 2010). Our study's overarching goal was to identify the target audience's level of knowledge by comparing the readability of patient-prepared informational leaflets (PIL) and health professionals' self-prepared practice guides (SmPC) in Turkish using mathematical formulae.

MATERIAL AND METHODS

The Turkish Medicines and Medical Devices Agency's (Türkiye İlaç ve Tıbbi Cihaz Kurumu; TITCK) "Turkish Pharmaceutical Market Monitoring Report-8, 2020 Market Status in terms of Sales Volume and Value" report from 2021 served as the foundation for our data. This report's sales data for 2020 was used to determine the top 20 medications, including those covered by private insurance and Social Security Institution (Sosyal Güvenlik Kurumu, SGK) (a total of 80 pharmaceuticals) and those supplied without a prescription (Table 1). (Barkanlığı, Sağlık, 2021). The most up-to-date SmPC and PIL details for the medications in this list were retrieved from the TITCK website (<https://www.titck.gov.tr/kubkt>). The review

only considered the most recent SmPC or PIL information for drugs if there are several versions available. The report includes "fortini multifi bre strawberry flavored, 200 ml," however it is not possible to analyze it since TITCK's website does not include SmPC- PIL information. There were a total of 80 drugs evaluated, 20 from each of the four groups. However, to avoid duplication of effort, only one drug with identical active ingredients and product names was included in the evaluations. For example, Parol 500 mg tablet, 20 tablets and Parol 500 mg tablet, 30 tablets are both included in the list. So, out of the 69 medicines that were considered, 10 had duplicate listings and 1 did not have SmPC-PIL data. The calculation of readability used the Ateşman and Bezirci-Yılmaz readability formulae. In 1997, Ateşman translated Flesch's readability for mula into Turkish and created his own readability formula (Ateşman, 1997).

The formula is: This is the formula for the readability score: $198.825 \text{ minus } 40.175\% \text{ of the word length (total syllables divided by total words) minus } 2.610 \text{ times the sentence length (total words divided by total sentences)}$. If the score goes up, it means the text is easier to read. Table 2 shows the required education levels and difficulty levels as a function of the scores. According to Bezirci and Yılmaz (2010), the readability formula known as Bezirci-Yılmaz was created in 2010 using the structure of the Turkish language; it was not adapted from any foreign formula. The findings show what kind of education is needed to understand the material (Table 3). Here is how the formula is determined: The formula for the readability score is the sum of the squares of the following: $(OKS \times ((H3 \times 0.84) + (H4 \times 1.5) + (H5 \times 3.5) + (H6 \times 26.25)))$. Here are the averages for various word counts: OKS for average word count, H4 for average number of 4-syllable words, H5 for average number of 5-syllable words, and H6 for average number of words with 6 or more syllables. We ignored the SmPC-PIL's product names and registration data so they wouldn't skew the results. The other components were evaluated using software created by Bezirci-Yılmaz (BET okunabilirlik.exe) (Bezirci & Yılmaz, 2010).

The education level's fractional results were rounded to the closest integer. Looking at the SmPC and PILs, we counted the amount of difficult terms. Any word

that wasn't in the basic 3000 was labeled as "difficult" according to the 2018 "Word Frequency Dictionary of Written Turkish" released by the Turkish Language Association. The data analysis was conducted using the SPSS 18 software tool. It was evaluated whether the data followed a normal distribution.

the education level needed for 13th-15th grade for Ateşman and undergraduate level for Bezirci-Yılmaz. You may find the word count, sentence length, difficulty level, syllable count, and polysyllabic word count of SPC-IFUs in the t Table.

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*	TOP 20 DRUGS PAID BY SGK	TOP 20 DRUGS PAID BY SPECIAL INSURANCES
PAROL 500 MG TABLET, 20 TB	PAROL 500 MG TABLET, 20 TB	CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB	CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB
CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB	DOLORDEX DRAJE, 20 DRAJE	PAROL 500 MG TABLET, 20 TB	AUGMENTIN BID 1000 MG FILM TABLET, 10 FILM TB
ARVELES 25 MG FILM TABLET, 20 TB	ARVELES 25 MG FILM TABLET, 20 TB	ARVELES 25 MG FILM TABLET, 20 TB	PAROL 500 MG TABLET, 20 TB
DOLORDEX DRAJE, 20 DRAJE	CORASPIN 100 MG ENTERIC COATED TABLET, 30 TB	BELOC ZOK CONTROLLED RELEASE FILM TABLET 50 MG 20 TB	TRANKO-BUSKAS 10 + 10 MG COATED TABLET (20)
BELOC ZOK CONTROLLED RELEASE FILM TABLET 50 MG 20 TB	DEVIT-3 IM/ORAL AMP.	DEVIT-3 ORAL DROPS 50.000 IU (15 ML)	ARVELES 25 MG FILM TABLET, 20 TB
NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TABLET	MAIEZIK 100 MG 15 FILM TABLET	DOLORDEX DRAJE, 20 DRAJE	RITALIN 10 MG TABLET (30 TB)
PAROL 500 MG TABLET (30 TABLET)	PAROL 500 MG TABLET (30 TABLET)	NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TB	BELOC ZOK CONTROLLED RELEASE FILM TABLET 50 MG 20 TB
ECOPHIN 100 MG ENTERIC COATED TABLET, 30 TABLET	ASPIRIN TABLET 2000.5G (20 TABLET)	ECOPHIN 100 MG ENTERIC COATED TABLET, 30 TABLET	AUGMENTIN BID 1000 MG FILM TABLET, 14 TABLET
LANSOR MICROPELLET CAPSULE 30 MG 28 CAP	VERMIDONE TABLET (30 TABLET)	LANSOR MICROPELLET CAPSULE 30 MG 28 CAP	DEVIT-3 ORAL DROPS 50.000 IU (15 ML)
MAIEZIK 100 MG 15 FILM TABLET	NOVALGIN 500 MG TABLET, 20 TB	PAROL 500 MG TABLET (30 TABLET)	DEVIT-3 IM/ORAL AMP.
TRAVAZOL LEATHER CREAM (15 G)	DEVIT-3 ORAL DROPS 50.000 IU (15 ML)	FORTINI MULTIFIBER STRAWBERRY FLAVORED, 200 ML	GERALGINE-K TABLET 20 TB
DEVIT-3 IM/ORAL AMP.	NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TB	INFATRIN 200 ML	DOLORDEX DRAJE, 20 DRAJE
FORTINI MULTIFIBER STRAWBERRY FLAVORED, 200 ML	CAIPOOL SUSPENSION	GLUFOR 1000 MG FILM TABLET (100 TABLET)	NEXIUM ENTERIC COATED PELLET TABLET 40 MG 28 TB
DEVIT-3 ORAL DROPS 50.000 IU (15 ML)	A-FERIN FORT FILM TABLET 30 TB	PLAVIX 75 MG 28 FILM TABLET	LYRICA 300 MG CAPSULES (56 CAPSULES)
INFATRIN 200 ML	NUROFEN COOL &amp; FLU 100MG/30MG FILM COATED TABLET (24 TABLET)	ALGEMIN 1000 MG 15 FILM TABLET	NEURONTIN 800 MG NOTCHED FILM COATED TABLET (30 TB)
GLUFOR 1000 MG FILM TABLET (100 TABLET)	TRAVAZOL LEATHER CREAM (15 G)	NOCOTROPIL FILM TABLET 800 MG 30 TB	MAIEZIK 100 MG 15 FILM TABLET
PLAVIX 75 MG 28 FILM TABLET	ECOPHIN 100 MG ENTERIC COATED TABLET, 30 TB	VENTOLIN INHALER 200 DOSES	XANAX 1MG 50 TABLET
AUGMENTIN BID 1000 MG FILM TABLET, 14 TABLET	VENTOLIN INHALER 200 DOSES	VENTOLIN INHALER 200 DOSES	BELOC ZOK CONTROLLED RELEASE FILM TABLET 25 MG 20 TB
NOCOTROPIL FILM TABLET 800 MG 30 TB			LANSOR MICROPELLET CAPSULE 30 MG 28 CAP
VENTOLIN INHALER 200 DOSES			PLAVIX 75 MG 28 FILM TABLET

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

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 & Yılmaz, 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 in-

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

RESULTS

Out of a total of 69 items, 138 SmPC-PIL were assessed. The calculation for the mean reading score was 43.8 ± 6.2 for Ateşman and 15 ± 2.4 for Bezirci-Yılmaz, respectively. This corresponds to

Table 4 shows that PILs are significantly shorter than SmPCs across all groups ($p=0.000$). Examining the ratio of difficult words in SmPC-PIL revealed that 97.09 ± 1.12 of SmPC and 97.50 ± 1.65 of PIL were comprised of such terms. This rate was actually greater in PILs, but the difference was not deemed significant ($p=0.083$). Both the Ateşman and Bezirci-Yılmaz

ratings differed significantly when looking at the readability of the SmPC and PIL ($p=0.007$ and $p=0.000$, respectively) (Table 5).

The purpose of preventing illness and promoting wellness (Kanj & Mitic, 2009). In health literacy, the idea of "readability" is directly tied to the degree to which the material is simple for the reader to understand and comprehend. The purpose of our research was to examine how well SmPC and PILs are able to be read. According to research, the majority of patients either failed to remember or misunderstood the instructions given to them by their doctors or other medical staff (Calkins et al., 1997; Makaryus & Friedman, 2005). Half of the doctor's words were forgotten by the patient five minutes after they left the exam room, according to the research.

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.

examination chamber (Kitching, 1990). Another research with 623 patients found that only 31% felt their doctor adequately educated them about the medication's potential negative effects

(Enlund, Vainio, Wallenius, & Poston, 1991). It is becoming more difficult for physicians to devote sufficient time to their patients and give them with the information they need as a result of rising workloads and the rising demand for health care, particularly in light of the COVID-19 pandemic (Auwal, Tanimu, Samira, & Hadiza, 2022; Desideri et al., 2021). This is why it's crucial to have clear and concise instructions printed on pharmaceutical packaging and given to patients in advance. It is expected that patients would be more accountable for their own health issues. According to our research, Ateşman needs an average of thirteenth to fifteenth grade to comprehend the texts, whereas Bezirci-Yılmaz needs an undergraduate degree. In 2020, 63% of Turkish residents were categorized as having low education levels, according to statistics from the Turkish Statistical Institute (Türkiye İstatistik Kurumu, 2020), meaning they had completed secondary school or less. According to the Türkiye İstatistik Kurumu (2020), just 16% of the population has completed schooling up to the 13th grade or above. Based on these numbers, it's clear that SmPC and PILs have been developed at a level above the comprehension of most people.

The results were very similar, however the Ateşman computation had somewhat better readability. As previously stated, the Ateşman readability for mula is a modification of the Flesch readability formula to Turkish (Ateşman, 1997), rather than a formula constructed totally in line with the Turkish language structure. The readability metric values are almost same in Turkish and English, despite the fact that the two languages are structurally distinct. One might argue that learning Turkish is more challenging than learning English due to the language's additive nature (Solak & Bayar, 2015). In 2010, Bezirci and Yılmaz created the Bezirci-Yılmaz readability for mula, a system that is more suited to the structure of the Turkish language (Bezirci & Yılmaz, 2010). Both formulae are often

employed in literature, but this one appears to be more suited to the structure of the Turkish language. Hence, our research made use of both formulations. When comparing PILs to SmPCs, the former has a much lower average word count, sentence length, and syllable count. But the texts did not reflect this shortness on the same degree as reading skill. In the Bezirci-Yılmaz calculation that was made according to the Turkish language structure, PILs were determined to be less legible, even though they were determined to have a higher Ateşman score.

thought to have a lower legibility. Furthermore, the terms that are deemed "difficult words" due to their absence from the basic PILs utilized 3,000 Turkish terms at a greater rate than SmPC, although both PILs and SmPC used over 97%. Looking at it this way, PILs are just condensed versions of SmPCs, not patient-friendly, easier-to-read texts. The most popular medicine categories, those available over-the-counter, and those covered by SGK and private insurance did not vary in terms of readability. In this case, it would be reasonable to produce more readable wording and to restrict the PILs of the most marketed pharmaceuticals without prescription. Certain standards should be established for SmPC and PILs. According to the 2005 European Union guidelines (Türkiye İlaç ve Tıbbi Cihaz Kurumu, 2007, 2008), the current standards in Turkey were released in 2007 and 2008. Detailed instructions on how to utilize SmPC and PIL subtitles, as well as instructions on how to choose the correct font, size, and paper type, are included in these guidelines. Conversely, recommendations such as "short sentences should be used" were not accompanied by details like the definition of "shortness," the amount of syllables, or the total word count. We propose that, considering the average level of knowledge in a given society, it is reasonable to assess SmPC and PILs using readability formulae that have been shown effective in the literature before putting

them into practice. There is a new idea in medical literature on readability (Ay & Duranoğlu, 2022). To our knowledge, no other research has looked at how readable SmPC and PILs are. Nevertheless, our study's primary shortcoming is that it just assesses readability, not intelligibility. Accordingly, further research is required, such as the Patient Education Materials Evaluation Tool (Vishnevetsky, Walters, & Tan, 2018), which assesses patients' levels of understanding. Regardless, our research is noteworthy since it is one of the first of its kind in this area. Preparing documents with short phrases and words with few syllables is necessary for boosting readability. Using a basic and straightforward language is also important. It is important to ensure that the materials intended for patients are written at a level that is accessible to all readers. The people responsible for writing these materials should have known better than to limit themselves to brevity when writing for medical professionals. Given the dynamic nature of health care delivery in the modern day, this strategy would be more suitable.

CONCLUSION

With regard to legibility, the PILs are on par with the materials designed for medical professionals. The original texts were condensed during the preparation of PILs in order to make them more understandable. Patients are expected to play a more active role in their own healthcare in today's system, thus it's important that PILs be written at a level that all segments can understand. Peer-review: evaluated by experts in the field. The participants' written permission was acquired as part of the informed consent process. Contributions from Authors: E.G., K.T., M.A.N., İ.B.Y.K. were involved in Study Conception/Design; E.G., K.T., M.A.N., İ.B.Y.K. were involved in Manuscript Drafting; and E.G., K.T., M.A.N., İ.B.Y.K. were involved in Final Approval and Accountability.

REFERENCES

1. Ateşman, E. (1997). Türkçede okunabilirliğin ölçülmesi. *Dil Dergisi*, 58(71-74).
2. Auwal, F. I., Tanimu, M., Samira, A.-A., & Hadiza, M. A. (2022). Assessment of knowledge and attitude of undergraduate students' of Ahmadu Bello University Zaria towards depression. *İstanbul Journal of Pharmacy*, 52(1), 96-100.
3. Ay, İ. E., & Duranoğlu, Y. (2022). Göz damlası prospektüslerinin okunabilirlik düzeyinin değerlendirilmesi. *Anatolian Clinic the Journal of Medical Sciences*, 27(1), 55-59.
4. Baker, D. W., Parker, R. M., Williams, M. V., & Clark, W. S. (1998). Health literacy and the risk of hospital admission. *Journal of general internal medicine*, 13(12), 791-798.
5. Bezirci, B., & Yilmaz, A. E. (2010). Metinlerin okunabilirliğinin ölçülmesi üzerine bir yazılım kütüphanesi ve Türkçe için yeni bir okunabilirlik ölçütü. *Dokuz Eylül Üniversitesi Mühendislik Fakültesi Fen ve Mühendislik Dergisi*, 12(3), 49-62.
6. Calkins, D. R., Davis, R. B., Reiley, P., Phillips, R. S., Pineo, K. L., Delbanco, T. L., & Iezzoni, L. I. (1997). Patient-physician communication at hospital discharge and patients' understanding of the postdischarge treatment plan. *Archives of Internal Medicine*, 157(9), 1026-1030.
7. Desideri, I., Francolini, G., Ciccone, L., Stocchi, G., Salvestrini, V., Aquilano, M., . . . Scotti, V. (2021). Impact of COVID-19 on patient– doctor interaction in a complex radiation therapy facility. *Supportive Care in Cancer*, 29(6), 2931-2937.
8. Enlund, H., Vainio, K., Wallenius, S., & Poston, J. W. (1991). Adverse drug effects and the need for drug information. *Medical care*, 29(6), 558-564.
9. Erdoğan, Ö. N., & Araman, A. O. (2017). Health beliefs and functional health literacy; Interaction with the pharmaceutical services. *İstanbul Journal of Pharmacy*, 47(2), 68-71.
10. Ilbars, H., & Özkan, S. (2020). Understanding of Turkish pharmacists health literacy knowledge, attitudes, and behavior. *İstanbul Journal of Pharmacy*, 50(1), 64-70