

# Readability levels of package leaflets of psychotropic drugs

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## SUMMARY

**Objective:** The readability of a text can be measured objectively using a series of mathematical formulas. Patients' proper understanding of a drug's effects and side effects is essential for treatment compliance in psychiatry. This study aimed to measure the readability level of the package leaflets of psychotropic drugs currently used in Turkey and to determine at what average age and education level were appropriate.

**Method:** Four main psychotropic drug groups, which are thought to be used more frequently in adult psychiatry, were included in this study. The most recent package leaflets of the drugs in these groups were obtained from the official websites of the Ministry of Health, the Turkish Medicines and Medical Devices Agency (<https://www.titck.gov.tr/kubkt>) and the relevant companies in the market, and their readability level was determined. The formulas developed by Ateşman and Bezirci-Yılmaz were used to evaluate readability levels in this study.

**Results:** The average Ateşman readability points were determined to be 48.2. From this, it was understood that an education at the level of the 13th-15th grade was necessary for the readability of the package leaflets. The average Bezirci-Yılmaz readability points were determined to be 13.2, indicating that an education at the level of 13th grade, or further education, was necessary for the readability of the package leaflets.

**Discussion:** The level of education required for readability of the psychotropic drug package leaflets was seen to be extremely high when the average level of education in Turkey was considered. Improving package leaflets' readability can reduce patients' concerns about psychotropic drugs by facilitating their understanding of the treatment. It can increase treatment compliance, thereby helping the recovery of mental health.

**Key Words:** Psychotropic drugs, package leaflet, readability

## INTRODUCTION

Readability first emerged as a concept in the USA at the beginning of the 19th century (1). Unlike legibility, which is determined by the stylistic features of a text such as a font and a page shape, readability is defined as whether the text can be easily followed and understood by the reader. The readability of a text can be measured objectively using a series of mathematical formulas based on the relationships between the number of syllables, words, and sentences (2). Many studies in literature have been

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conducted to determine the readability of scientific texts (3). Some of these studies have been about the readability of consent forms, drug package leaflets and patient information texts, which are essential for patients to have the correct information (4).

Package leaflets, in other words, instructions for use, are explanatory-informative texts (5). When a package leaflet is read without consulting a doctor, patients can change the drug dose themselves or stop taking it. Although package leaflets are used

as a natural part of psychoeducation, some of the information in package leaflets (expected side-effects of the drug, manner of use, etc.) is known to be given to patients and their relatives in the form of a brochure in various clinics. Therefore, if package leaflets are written in simple and understandable language, they can potentially be used in the future as a part of psychoeducation, which is a crucial component of non-pharmacological treatments in the mental health field. In psychiatry, giving information about the drug's effects and side effects is vital in the content of psychoeducation interventions directed at the patient and their family (6). It should be said that even in psychotic disorders, now considered neurodevelopmental disorders and whose treatment is primarily mediated by drugs at every stage, the physician's duty does not end with the proper drug selection because non-compliance with drug therapy is a common problem in these patients. For example, previous studies in this field have reported that in schizophrenia and other psychotic disorders, non-compliance with antipsychotic drugs varies between 11% and 80% (7). In more comprehensive studies, the reasons for drug non-compliance, not only in psychotic disorders but also generally in patients with psychiatric disorders, are fears associated with drug use, side effects related to the drugs, problems experienced in adhering to the drug regimen, being insufficiently informed about the treatment or misinterpretation of the treatment, attitudes of the patient and those close to them about mental health diseases and drug treatment, and difficulties thought to be created in societal life by drug use (8).

In the "2016 Education at a Glance" report of the Organisation for Economic Co-Operation and Development (OECD), Turkey was ranked 35 out of the 38 OECD member countries (9). According to the research entitled "Average and Expected Years of Schooling by Provinces in Turkey", conducted in 2016 by TOBB Economics and Technology University Social Policies Application and Research Centre and Pamukkale University, the average years of education was determined as 6.51 for the population aged  $\geq 25$  years (10). When these data are considered, it can be considered even more important that public information texts in Turkey are written to be as readable as possible.

This study aimed to measure the readability level of psychotropic drug package leaflets currently used in Turkey and determine at what average age and educational level is appropriate.

## METHODS

*Ethical approval:* Approval for this study was granted by the Non-Interventional Clinical Research Ethics Committee of Sivas Cumhuriyet University (decision no: 2022-02/01).

*Information on readability formulas:* Parameters such as the number of syllables, words, and sentences in the text play a role in the basis of the formulas providing objective measurement of readability which are accepted in the scientific world. More than two hundred formulas and thousands of studies have been published in this field, especially for English (1). Flesch developed the first essential readability formula accepted in literature in 1948 (11). In the following years, different indexes were developed, such as the Flesch-Kincaid, Klare, Dale Cale, Gunning Fog, and Fry (12) and McLaughlin (13) readability formulas. For the evaluation of readability levels in the current study, the formulas developed by Ateşman (14) and Bezirci-Yılmaz (2) were used.

*Ateşman Readability Formula:* Readability score =  $198.825 - 40.175 \times \text{word length (total syllables / total words)} - 2.610 \times \text{sentence length (total words / total sentences)}$ .

This formula, calculated as stated above, provides a readability score of 0-100 points. The scores are evaluated as text readability is "very difficult":1-29 points, "difficult":30-49 points, "moderately difficult":50-69 points, "easy":70-89 points, and "very easy":90-100 points (14). In other words, unlike the Bezirci-Yılmaz formula, the higher the score, the easier the readability. The points obtained can also be determined at what education level the text can be read (Table 1).

*Bezirci-Yılmaz Readability Formula:* Readability score =  $\sqrt{\text{AWC} \times [(\text{S3} \times 0.84) + (\text{S4} \times 1.5) + (\text{S5} \times 3.5) + (\text{S6} \times 26.25)]}$ .

**Table 1.** The education level corresponding to the points obtained with the Atesman readability formula

Points	Education level
90- 100	Readable by an individual with education in primary school 4th grade and below
80- 89	Readable by an individual with education in 5th or 6th grade
70- 79	Readable by an individual with education in 7th or 8th grade
60- 69	Readable by an individual with education in 9th or 10th grade
50- 59	Readable by an individual with education in 11th or 12th grade
40- 49	Readable by an individual with education in 13th -15th grade
30- 39	Readable by an individual with education at the undergraduate level
≤29	Readable by an individual with education at the postgraduate level

AWC: Average Word Count

H3: average number of 3-syllable words, H4: average number of 4-syllable words, H5: average number of 5-syllable words, H6: average number of 6-syllable words.

In the formula calculated as stated above, a readability score is obtained according to the number of words in sentences and syllables in words. Increased points in this formula indicate more difficult readability. In addition, it can be determined that the readability of a text examined according to this formula corresponds to which education level in Turkey (2) (Table 2).

**Table 2.** The education level corresponding to the class/points obtained with the Bezirci-Yilmaz readability formula

Grade	Education level
1- 8	Primary school
9- 12	Middle school (High school)
12- 16	Further education
16+	Academic level education

*Drug groups and package leaflets:* In all drug packaging, there is a package leaflet stating what the drug is, how it should be used, what should be considered before use, potential side effects, how it should be stored, and licence information. Package leaflets in Turkey are used in two ways, as brief product information and instructions for use. The brief product information represents the basis of the information given to healthcare professionals about how the medical product is to be used safely and effectively. The instructions for use are prepared for the patients. Therefore, all the package leaflets used in this study were examined based on the instructions for use.

Four main psychotropic drug groups, which are thought to be used more frequently in adult psychi-

atry, were included in this study. The most recent package leaflets of the drugs in these groups were accessed from the official websites of the Ministry of Health, Turkish Medicines and Medical Devices Agency (<https://www.titck.gov.tr/kubkt>) and the official websites of the relevant companies in the market (15,16). The readability level of all these package leaflets was determined. Different doses or forms (tablet, suspension, injection) of the same drug were examined as different package leaflets. In contrast, package leaflets with different numbers of tablets in the same form and dose would have the same readability, so only one was included in the study.

A total of 616 package leaflets were included in the study, separated into four groups of psychotropic drug groups antidepressants (n:176), antipsychotics (n:264), mood stabilizers (n:84), and anxiolytics and hypnotics (n:92).

The package leaflets were uploaded to the Microsoft Notepad program in an electronic medium. Before evaluation, the headings and the licence information were removed from the package leaflets to avoid these affecting the readability level. In addition to the formulas in the evaluations, the computer program produced by Bezirci-Yilmaz was used to calculate the average Bezirci-Yilmaz readability points and the average Atesman readability points. The fractional points related to the education level were rounded to the nearest whole number.

## RESULTS

The average Atesman readability points were determined to be 48.2 (Table 3). From this, it was understood that an education at the level of the 13th-15th grade was necessary for the readability of the package leaflets (Table 1). The average Bezirci-

**Table 3.** Average readability points for the psychotropic drugs

Drug groups (n= 616)	Atesman average readability points	Bezirci- Yilmaz average readability points
Antidepressants (n= 176)	48.5	13.0
Antipsychotics (n= 264)	48.4	13.4
Mood stabilizers (n= 84)	46.8	13.5
Anxiolytics-Hypnotics (n= 92)	48.9	12.8
Total average readability level	48.2	13.2

n: Count of package leaflets

Yilmaz readability points were determined to be 13.2 (Table 3). From this, it was understood that an education at the level of 13th grade, or further education, was necessary for the readability of the package leaflets (Table 2). According to these findings, the results obtained with the two readability formulas were consistent with each other. The easiest readability of all the package leaflets was determined to be an anxiolytic-hypnotic with the highest point of 63.9 according to the Atesman readability formula. An education level of 9th or 10th grade was necessary for this readability. The same package leaflet was determined with the lowest point of 7.3 in the Bezirci-Yilmaz readability formula. Thus, according to these formulas, it was understood that for the easiest readability of the psychotropic drug package leaflets examined in this study, education of at least seven years was required. The most difficult readability of the package leaflets was determined to be a depot antipsychotic drug with the lowest point of 39.1 according to the Atesman readability formula, for which university-level education was required. The same package leaflet scored the highest point of 17.1 in the Bezirci-Yilmaz readability formula. Therefore, it was understood that the most difficult readability of the psychotropic drug package leaflets required an academic level of education. The average points of the psychotropic drug groups and the Atesman

and Bezirci-Yilmaz readability points are shown in Tables 3 and 4.

## DISCUSSION

In medicine, informing patients correctly about drug treatment is a fundamental deontological principle regarding patient rights and proper treatment process management. This principle is regularly applied in clinical practice and is perhaps more important in mental health than in other medical specialities. Providing correct information in this field strengthens the therapeutic collaboration between patient and physician by establishing trust, which is the basis of the mental health of every individual. Moreover, it seriously affects the whole treatment process, especially in mental health disorders in which impaired treatment compliance can impair the patient's ability to evaluate reality.

There are few studies related to readability in the international literature on mental health. In a 2007 study by Christopher et al., which examined the readability of consent forms used in the mental health field to provide information, the general average readability points of the consent forms were reported to be at the level of 12-14.5 grades.

**Table 4.** Distribution of the package leaflets according to the Atesman and Bezirci-Yilmaz readability levels

	Primary school (1 -8) n (%)	Middle school (9 -12) n (%)	Further education (13 -15) n (%)	Academic (?16) n (%)
<b>Atesman formula</b>				
Antidepressants (n= 176)	0 (0)	63 (36)	113 (64)	0 (0)
Antipsychotics (n= 264)	0 (0)	86 (33)	172 (65)	6 (2)
Mood stabilizers (n= 84)	0 (0)	21 (25)	58 (69)	5 (6)
Anxiolytics-Hypnotics (n= 92)	0 (0)	22 (24)	70 (76)	0 (0)
Total (n=616)	0 (0)	192 (31)	413 (67)	11 (2)
<b>Bezirci- Yilmaz formula</b>				
Antidepressants (n= 176)	7 (4)	57 (32)	98 (56)	14 (8)
Antipsychotics (n= 264)	3 (1)	54 (21)	183 (69)	24 (9)
Mood stabilizers (n= 84)	2 (2)	19 (23)	54 (64)	9 (11)
Anxiolytics-Hypnotics (n= 92)	6 (6)	18 (20)	68 (74)	0 (0)
Total (n=616)	18 (3)	148(24)	403 (65)	47 (8)

The duration of the education is given as years.

n: Count of package leaflets.

In addition, studies have determined that as the risk level increased, so the average readability points increased, in other words, readability became more difficult. In a study approved by the Massachusetts Mental Health Department, in which approximately 35% of the participants had not attended high school, 37% had attended high school, and 28% had further education beyond 12th grade, it was stated that the readability of consent forms used to provide information was low. Thus it was emphasized that there was an incompatibility between the readability of the consent forms and the predicted education level of potential participants, and there was stated to be a great need for methods to reduce the complexity of the forms (17).

In 2011, Shiffman et al. conducted a study measuring what consumers understood after reading an antidepressant leaflet. Of the 52 participants, 45 were high school graduates, and 7 had less than high school graduates. It was found that the participants understood only 40% of the information that could be considered significant, and most of them needed help understanding the warnings and instructions about severe medical consequences in 24 minutes (18).

The average readability of smartphone applications used in mental health was determined by Robillard J.M. et al. in 2019 to be at the level of 13.8 grade (13.8 iOS, 13.7 Android) for privacy policies and 15.2 (15.5 iOS, 13.9 Android) for contract conditions. In other words, an education of approximately 14 years was necessary to read the text related to privacy policies, and an education of approximately 15 years to read the text related to the contract conditions. Therefore, it was emphasized that as most privacy policy and contract conditions texts were written at a reading level beyond high school, it would take more work for users to understand these legal documents fully. Previous studies in this field have also reported that the average readability level of privacy policies used in health applications is very much beyond the reading level of the typical user (19).

In a 2021 study by Jilka S. et al., the readability was investigated of a smartphone mental health appli-

cation related to depression, and the readability of the application was determined to be consistent with the 8th grade reading level recommended by the FDA. However, the same study also stated that the National Adult Literacy Research had determined that approximately one in four adults in the USA could not read or understand written material above the level of 5th grade. It was also stated that approximately 15%, or 5.1 million adults in the United Kingdom, had a literacy level expected in a child aged 11 years or younger (20).

There are some recent studies in literature related to the use of Turkish language readability formulas in medical texts. In a 2021 study by Ay and Duranoğlu, the readability level of 80 eye drop package leaflets was evaluated, and the average readability was found to be at the level of 13 years of education (university-level). When the average education level in Turkey is considered, this was found to be very high (4).

In a 2011 study conducted by Tonbuloğlu in which a total of 780 pages of approximately 300 package leaflets, which predominantly contain words of French origin, were analyzed in terms of the terms used, the package leaflets were also analyzed phonetically, morphologically and semantically. As a result of the study, it was found that although some of the medical terms used in the package leaflets have meaningful equivalents in Turkish, more complex expressions were used. A comparative study was also carried out in the same study. It was comparatively demonstrated that in package leaflets published in France, French terms were predominantly used instead of Latin terms; almost no terms from foreign languages other than French were used. Simple sentence types were preferred in short and plain language, which made it easier for people outside the field to understand the package leaflets. The same study also considered officials' opinions from some well-known pharmaceutical companies in Turkey. One of the officials stated that they also had difficulty understanding the package leaflets of some drugs and that the subjects written in the package leaflets (even those intended for the general public) require a deep knowledge of medicine and pharmacy (21).

In our study, the most hard-to-read package leaflet to read was a depot (long-acting injectable) antipsychotic drug, which requires an undergraduate-level education according to the Ateşman readability formula and an academic level education according to the Bezirci-Yılmaz readability formula. Although there are debates about the extent to which depot antipsychotics are associated with fewer relapses and rehospitalizations, the most significant advantage of this medication over oral medication is that it facilitates adherence to medication intake. Treatment nonadherence is very common in patients with schizophrenia and is frequently the cause of relapse (22). Studies have emphasized that treatment nonadherence is also an essential problem in patients with bipolar affective disorder, and it is reported that treatment nonadherence is observed between 20-60% of the patients (23). Some systematic reviews have reported that second-generation long-acting antipsychotics, especially risperidone and aripiprazole LAI, may be a safe and effective alternative to oral drugs in treating bipolar disorder (24). Based on all this information, the readability of depot antipsychotics should be expected to be much easier since the patient groups in which these drugs are preferred are those with whom clinicians have the most difficulty regarding insight and treatment compliance. If patients, especially those with psychotic disorders and bipolar affective disorder, who have more difficulty in achieving insight and treatment adherence, can simply and accurately understand information such as what the medications prescribed to them are, how to use them, what should be considered before use, possible side effects and how they should be stored, this may have a positive impact on the patient-physician relationship.

When we look at the historical development of the patient-physician relationship, we see that the paternalistic understanding of medicine, which was dominant from Ancient Egypt, i.e. 4000 BC, until the Greek Enlightenment, i.e. 100 BC, has been replaced by egalitarian approaches that centre the patient today (25). Although psychotherapy is not performed in every clinical interview in psychiatry, it is evident that psychotherapeutic interventions, including psychoeducation under ideal conditions, have an essential place in treatment success.

Whether this is from the dynamically oriented or cognitive-behavioural school, the existing literature and our clinical experiences show us that concepts such as therapeutic alliance and working alliance constitute the basis for the success of today's psychotherapies (26,27). On the other hand, as our study reveals, unlike the short product information prepared for healthcare professionals, the difficult readability of the package leaflets prepared for patients does not seem to be compatible with the nature of the egalitarian relationship between patient and physician.

According to the results of the current study obtained with both the Ateşman and the Bezirci-Yılmaz formulas, at least 7 years of education, and an average of 13 years, in other words, university-level, was determined to be necessary to be able to read the 616 package leaflets examined. When it is considered that the average level of education in Turkey is 6.5 years (10), it can be thought that it would be more appropriate for package leaflets to be written at a primary school level.

### **Strengths and limitations of the study**

According to our literature review, our study is the first study in Turkey and in the international literature to evaluate all psychotropic drug package leaflets in four main groups such as antipsychotics, antidepressants, anxiolytics/hypnotics and mood stabilizers with readability formula.

However, there were also some limitations to this study. The formulas used for readability focus on quantitative aspects (such as the number of words, syllables, and sentences) rather than qualitative features, such as the meanings of words or sentences and their usability in that language. Therefore, a quantitative calculation alone cannot be expected to evaluate all the dimensions of readability of a text in that language. In addition to the formulas accepted in the literature for this purpose, a qualitative analysis by having patient populations read the relevant texts would enable a more comprehensive evaluation to be carried out. Finally, although a significant number of psychotropic drug package leaflets in a broad spectrum were examined in this study, there may have been a small

number of package leaflets that could not be accessed with an internet search.

In the literature, methods are also developed to overcome the difficulties experienced with the readability of package leaflets. In 2017, Segura-Bedmar et al. developed the EasyDPL (Easy Drug Package Leaflets) corpus to improve the readability of package leaflets written in Spanish. This corpus comprises 1400 adverse drug effects, their simplest synonyms, and 306 manually explained leaflets (28).

Improving package leaflets' readability can reduce patients' concerns about psychotropic drugs by facilitating their understanding of the treatment. It can increase treatment compliance, thereby helping the recovery of mental health. It would also decrease the legal problems that mental health providers may encounter because of misunderstandings by patients and their families and may reduce some repeated presentations of patients.

Although hard-to-read package leaflets prepared for patients are a general problem in many countries, there are methods developed to facilitate readability. Therefore, we think that the development and use of applications for both semantic and syntactic simplification of these texts is a necessity for public health.

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**Data availability statement:** The data in the article is fully public.

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