

# Evaluation of the readability levels of patient information leaflets of frequently prescribed drugs in rheumatology practice

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## Abstract

The development and use of new drugs have accelerated in proportion to the increase in understanding of the pathogenesis of rheumatological diseases. In the treatment of rheumatological diseases, regular and proper use of drugs prevents disease progression and protects the patient from potential exacerbations and complications. The readability of patient information leaflets (PILs) increases treatment compliance. In this study, it was aimed to evaluate the readability levels of PILs of frequently prescribed drugs in rheumatology practice. A total of 182 frequently prescribed medications in rheumatology practice were randomly selected. The PILs of these drugs were scored according to Ateşman and Bezirci-Yılmaz readability scales and their readability levels were thus determined. It was determined that the PILs could be read with 11-12 years of education and high school education on average according to Ateşman and Bezirci-Yılmaz readability scales respectively. Considering the fact that the mean schooling level in Türkiye is 6.5 years, the readability levels of the PILs of frequently prescribed medications in rheumatology practice are well above this level. It is suggested that the current readability of the PILs is adjusted in accordance with the patients' level of understanding and education and arrangements to increase the readability levels are made.

**Keywords:** Rheumatology, patient information leaflet, readability level

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## Introduction

Rheumatological diseases are chronic inflammatory diseases that cause loss of function at different levels and decrease in quality of life and may increase morbidity and mortality. In the treatment of these diseases, the aim is to achieve an early and permanent reduction in disease activity and, if possible, remission [1,2]. Disease-modifying anti-rheumatic drugs (DMARD) form the basis of the treatment of rheumatological diseases. The introduction of biological (b) DMARD agents after conventional synthetic DMARDs (csDMARDs) has started a new era in the treatment of inflammatory arthritis. bDMARDs work through specific cytokines and pathways involved in the pathogenesis of diseases or through mechanisms directed against cellular targets. The efficacy and safety of many bDMARDs such as anti-TNF agents (adalimumab, etanercept, infliximab, golimumab, certolizumab), B-cell blockers (rituximab), T-cell blockers (abatacept), IL-6 blockers (tocilizumab), IL-17 blockers, IL-12 and IL-23 blockers, JAK-kinase inhibitors (tofacitinib, baricitinib) have been well demonstrated in rheumatological patients. Biosimilar agents of originator drugs have also started to be used after bDMARDs [3-7]. bDMARDs and biosimilar agents are important treatment options in resistant patients who cannot be treated with medications within the csDMARD category [5,8]. Anakinra and canakinumab are Interleukin-1 (IL-1) antagonist drugs for the treatment of autoinflammatory diseases such as Familial Mediterranean Fever (FMF) [9]. Used in systemic lupus erythematosus (SLE), belimumab is a monoclonal antibody against B-lymphocytes that blocks B-cell growth factors [10]. Cyclophosphamide, azathioprine, mycophenolate mofetil and calcineurin inhibitors (cyclosporine, tacrolimus) are immunosuppressive drugs prescribed in many rheumatic diseases such as connective tissue diseases and vasculitis, especially in the presence of life-threatening organ involvement [11]. Steroids can be used both as immunosuppressive and like DMARDs at low doses as in rheumatoid arthritis. Colchicine is still an effective and current medication employed in gout arthritis and FMF. Colchicine supplied

from abroad may also be used before anti-IL-1 treatments when locally-supplied colchicine is insufficient or cannot be tolerated. Allopurinol and febuxostat, which are inhibitors of xanthine oxidase, are prescribed in gout arthritis as uric acid lowering drugs (ULD) that work by reducing uric acid synthesis [12]. Non-steroidal anti-inflammatory drugs (NSAIDs) are used in many diseases in rheumatology practice, especially in spondyloarthropathies. Although fibromyalgia is not an inflammatory rheumatological disease, it may be comorbid with rheumatic diseases, and patients with fibromyalgia can present to rheumatology outpatient clinics with complaints of pain, and rheumatologists can prescribe drugs for fibromyalgia. Osteoporosis may occur during the course of rheumatological diseases or develop due to the use of medications, and treatment of osteoporosis is also often included in rheumatology practice.

Some patients may be willing to learn the side effects, method of use, and dose of the drugs they are prescribed in detail from the patient information leaflets (PILs). Some other patients stop taking the medication or change the dose without informing the physician after they have read the PIL. PILs should thus be understandable by patients.

The degree of understandability of a written text by the reader is assessed based on the text's readability level [13]. Readability level of a written text is determined through the use of some scales whose power is demonstrated with scientific studies. These scales calculate the readability score by using parameters such as the number of sentences, words, and syllables in the text. Ateşman and Bezirci-Yılmaz readability scales are often utilized for Turkish texts [14,15].

This study aims to measure the readability levels of PILs of frequently prescribed medications in rheumatology practice and determine the age and education level to which these PILs are appropriate.

## Materials and Methods

This study was carried out according to the decision of Afyonkarahisar Health Sciences University Clinical Research Ethics Committee dated 30.02.2023 and numbered 2023/74.

A total of 182 frequently prescribed drugs in rheumatology practice were randomly selected. The readability scores of the PILs of these drugs were calculated. These medications were divided into 8 groups: conventional synthetic DMARDs (csDMARDs), biologic DMARDs (bDMARDs), targeted synthetic DMARDs (tsDMARDs), immunosuppressive drugs, NSAIDs, FMF-gout arthritis drugs, fibromyalgia drugs, and osteoporosis drugs. The mean readability levels of these drug groups were evaluated within and among the groups. The readability levels of the PILs were measured based on the text that remained after the headings and authorization details at the end had been removed.

Many scales are utilized to determine the

readability level of a text. These scales provide a mean score based on parameters such as the number of words, sentences, and letters in the text. In this study, the readability levels of the PILs of the relevant drugs were evaluated by using Ateşman and Bezirci-Yılmaz readability scales.

In Ateşman readability scale, the score is between 0 to 100. Scores closer to 100 are defined as easier to read while those toward 0 are more difficult to read. Ateşman readability score calculation formula:  $RS=198.825-(40.175 \times X1)-(2.610 \times X2)$

RS: readability score

X1: Total syllable number/Total word number

X2: Total word number/Total sentence number

**Table 1.** Atesman readability scores and relevant required education level.

Readability Score	Education Level
90–100	Can be read by a person with education up to the 4 <sup>th</sup> grade of primary school.
80–89	Can be read by a person with education at the 5 <sup>th</sup> or 6 <sup>th</sup> -grade level.
70–79	Can be read by a person with education at the 7 <sup>th</sup> or 8 <sup>th</sup> -grade level.
60–69	Can be read by a person with education at the 9 <sup>th</sup> or 10 <sup>th</sup> -grade level.
50–59.	Can be read by a person with education at the 11 <sup>th</sup> or 12 <sup>th</sup> -grade level.
40–49	Can be read by a person with education at the 13 <sup>th</sup> or 15 <sup>th</sup> -grade level.
30–39	Can be read by a person with education at the undergraduate level.
≤29	Can be read by a person with education at the graduate level

Table 1 shows Ateşman readability scores and relevant required education level.

On the other hand, Bezirci-Yılmaz readability scale considers a text difficult to read as the readability score increases while texts receiving lower scores are deemed easier to read. Bezirci-Yılmaz readability score calculation formula:

$$RS = \sqrt{OKS \times ((H3 \times 0,84) + (H4 \times 1,5) + (H5 \times 3,5) + (H6 \times 26,25))}$$

RS: readability score

OKS: mean word number

H3: mean 3-syllable word number

H4: mean 4-syllable word number

H5: mean 5-syllable word number

H6: mean +6-syllable word number

Table 2 shows Bezirci-Yılmaz readability scores and relevant required education level.

The software developed by Bezirci-Yılmaz was

utilized to calculate readability scores with the formulas.

### Statistical Analysis

Categorical variables were presented as percentage and frequency. Continuous variables were provided as mean and standard deviation. ANOVA test was used to compare continuous variables between groups. Statistical analyses were performed with SPSS 26.0 package program. All *p* values were two-sided and values with *p*<0.05 were considered statistically significant.

### Results

A total of 182 PILs were used in the study. The mean readability score of these PILs was 58.42±7.62 according to Ateşman readability scale. On average, these PILs require 11-12 years of education. The score was 9.95±2.52 when calculated with Bezirci-Yılmaz readability scale. The corresponding education level is the secondary school (high school) (Table-3).

**Table 2.** Bezirci-Yılmaz readability scores and relevant required education level.

Readability Score	Education Level
1-8	Primary school
9-12	Secondary school (High school)
13-16	Undergraduate
16+	Graduate

**Table 3.** Mean readability scores of frequently prescribed drugs in rheumatology practice based on Ateşman and Bezirci-Yılmaz scales and corresponding education levels.

	Number	Minimum	Maximum	Mean (Standart Deviation)	Educational Status
ATEŞMAN	182	40.54	78.94	58.4238±7.62	11-12 years
BEZİRCİ-YILMAZ	182	5.10	15.71	9.9595±2.52	Secondary School (High School)

These medications were divided into 8 groups: csDMARDs (n:20), bDMARDs (n:32), tsDMARDs (n:3), immunosuppressive drugs (n:26), NSAIDs (n:45), FMF and gout arthritis drugs (n:7), fibromyalgia drugs (n:18), and osteoporosis drugs (n:31).

Among these groups, the ones that required the lowest education level to be read and understood were osteoporosis drugs and targeted synthetic DMARDs according to Ateşman readability scale and targeted synthetic DMARDs according to Bezirci-Yılmaz readability scale. According to the Ateşman readability scale, the education levels required for reading and comprehension of the drug groups other than osteoporosis drugs and targeted synthetic DMARDs are at the 11th or 12th grade level. According to the Bezirci-Yılmaz readability scale, the education levels required for reading and comprehension

of the drug groups other than targeted synthetic DMARDs are at the Secondary School (High School).

Figure 1 and 2 present the mean scores of the above-mentioned drug groups according to Ateşman and Bezirci-Yılmaz readability scales along with their comparison. Table 4, on the other hand, provide corresponding education levels for the mean scores of the drug groups.

### Discussion

A written text's value is determined by how much of it can be understood by the reader as much as it depends on the contents. The meaning of a written text is only as much as the reader understands. Since the beginning of 1950, many readability scales have been developed to determine text's understandability by readers. Flesch Reading Ease Score and the Gunning Fog

**Table 4.** Corresponding education levels for the mean scores of the drug groups frequently prescribed in rheumatology practice.

	<b>Bezirci</b>	<b>Ateşman</b>
<b>Osteoporosis Drugs</b>	Secondary School (High School)	At the 9th or 10th-grade level.
<b>NSAIDs</b>	Secondary School (High School)	At the 11th or 12th-grade level
<b>Conventional Synthetic DMARDs</b>	Secondary School (High School)	At the 11th or 12th-grade level
<b>Biologic DMARDs</b>	Secondary School (High School)	At the 11th or 12th-grade level
<b>Targeted Synthetic DMARDs</b>	Primary School	At the 9th or 10th-grade level
<b>Immunosuppressive Drugs</b>	Secondary School (High School)	At the 11th or 12th-grade level
<b>FMF-Gout Arthritis Drugs</b>	Secondary School (High School)	At the 11th or 12th-grade level
<b>Fibromyalgia Drugs</b>	Secondary School (High School)	At the 11th or 12th-grade level

Index are some examples. These scales use the number of sentences, words, and syllables in a text and their proportion to each other in order to determine the readability level [16].

Each language has unique characteristics, and languages thus are different from each other. Works on readability scales for Turkish texts started in the early 1990s. Ateşman and Bezirci-Yılmaz readability scales are the most common

alternatives for Turkish texts. Ateşman defined readability as texts being easy or difficult to be understood by the reader [14,15].

Patient information leaflets are written texts providing information about medications to patients. Patients may sometimes misunderstand PILs or they may be confused due to insufficient and missing information.

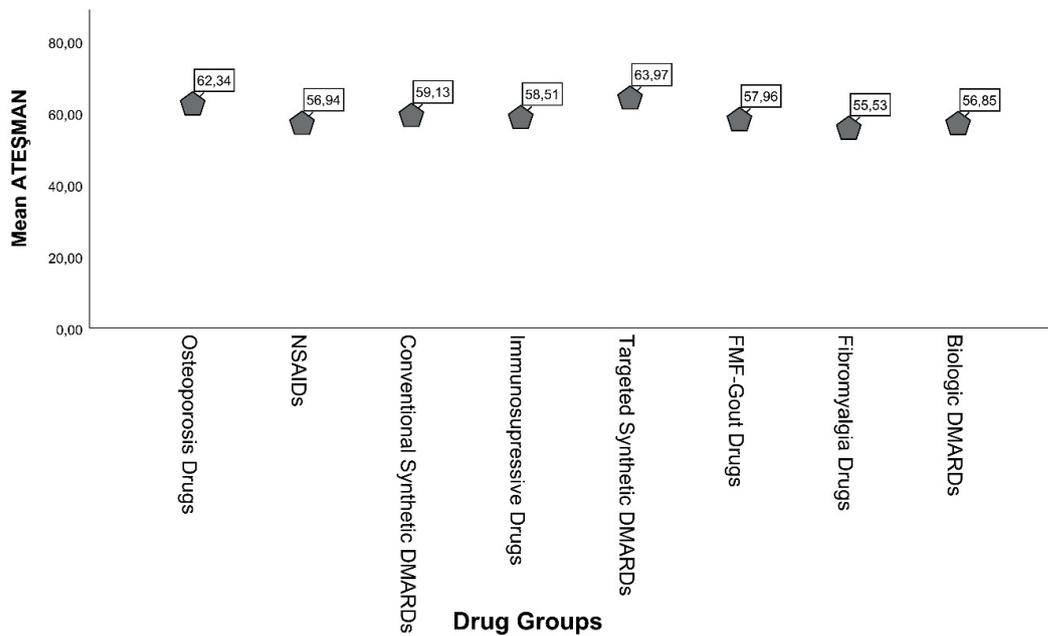


Figure 1. Mean scores of the drug groups according to Ateşman readability scale.

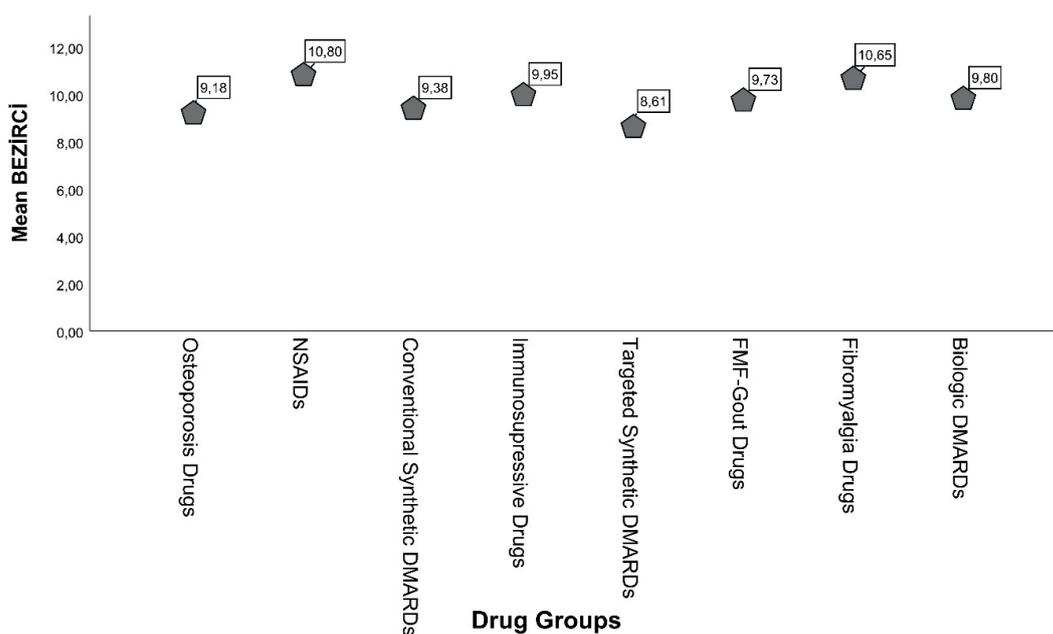


Figure 2. Mean scores of the drug groups according to Bezirci-Yılmaz readability scale.

A study by Sayın Kasar K. et al., where antihypertensive medication errors in elderly individuals were examined showed that 57% of the patients made medication errors. The medication error rate was significantly higher in women, people taking three and more drugs, people using other drugs in addition to the antihypertensive, and people that don't read the PILs of the drug they are taking. 32% of those who don't read the PILs said that it is because they can't understand what is in the PILs [17]. As demonstrated also with this study, the more difficult it is to understand PILs, the less the patients benefit from them and the higher the likelihood of medication error by the patients.

A study by Sarı A. et al., where they evaluated the readability levels of PILs of antihypertensive drugs determined that an average of 11-12 years of education, i.e. high school education, is required in order to read and understand the PILs of antihypertensive drugs. This study proved that PILs of drugs for hypertension, which is a quite common condition in society, are prepared for a higher education level than the average level of education in Türkiye [18].

The literature review for this research did not provide a Turkish study on the readability levels of PILs of drugs used in rheumatology practice. In the oral presentation at the National Rheumatology Congress in 2021, Tazegül G. et al., evaluated the readability levels of informed consent forms prepared by the Turkish Rheumatology Association (TRD) for 26 different drugs and stated that TRD informed consent forms required 11-14 years of education to be understood by the reader and that the readability of the current informed consent forms must be increased. Also in the oral presentation titled "Turkish readability levels of informed consent forms used for biological treatments of autoimmune diseases" by Tazegül G. et al., at the 8th Fırat Rheumatology Symposium in 2021, eight informed consent forms created for anti-TNF group drugs, anakinra, baricitinib, belimumab, rituximab, tofacitinib, and vedolizumab were evaluated and found to require at least graduate level education, and the authors suggested that the readability of the current informed consent forms must be enhanced.

In a study by Pires C. et al. with 63 individuals including physicians, pharmacists, and potential users, participants' accessibility to, and comprehensibility of, the PIL for diclofenac 12.5 mg tablets was evaluated according to the readability guideline of the European Medicine Agency (EMA). Despite the fact that almost all (85%) of the 20 potential users were educated above the 9th grade, the majority of them (95%) had, at least, one PILs interpretation issue, mainly related to the comprehension of technical terms; regarding the readability assessment of the PILs for diclofenac 12.5 mg tablets, the authors concluded that the method proposed in the EMA guidelines might not be as effective as expected and could be enhanced for safer use [19]. In a study by Arandy D.A. et al., in which they compared PIL contents of locally-supplied and imported NSAIDs, the researchers evaluated the PILs for a total of 35 NSAIDs, 18 locally-supplied and 17 imported, containing 9 different active ingredients. It was demonstrated in the study that the PILs of the locally-supplied NSAIDs provided less information in comparison with imported NSAIDs, and it was therefore suggested that both the Palestinian authorities and the manufacturers make appropriate arrangements to improve the content and quality of the information in PILs of locally-supplied NSAIDs [20]. In our study, we determined that the PILs of NSAIDs that we frequently use in rheumatology practice required 11-12 years of education, i.e. high school education. NSAIDs are medications that may have serious side effects and are common in society. When patients use NSAIDs at inappropriate doses or in conditions when NSAIDs are contraindicated or in combination with drugs such as warfarin and acetylsalicylic acid that may amplify the side effects of NSAIDs. Our study found that the PILs of NSAIDs that are used by people of all ages and for many different reasons required knowledge well beyond the average education level in Türkiye.

In a survey by Oton T. et al., where they assessed the experiences and needs of patients receiving methotrexate, their general treatment, and the quality of the information provided by their rheumatologist, 80% of the respondents said they had read the PILs and 62% of them found it

helpful while only 15% of all respondents did not find the PILs functional [21]. In our study, we also found that the level of readability of the PILs of csDMARDs such as methotrexate, leflunomide, and sulfasalazine corresponded to the education level of 11-12 years, *i.e.* high school education. We may face life-threatening conditions due to methotrexate intoxication when patients don't have a sufficient understanding of how to use the medication that should be taken every week. Rheumatologists provide information to patients about teratogenic drugs such as methotrexate and leflunomide; however, patients turn to the PILs to get information when physicians cannot allocate enough time to patients at outpatient clinics because of intense working conditions, and we thus believe that this may lead to problems due to insufficient understanding of the PILs of these drugs since a complete and thorough understanding of these PILs requires an education level beyond the average education level in Türkiye.

In a study by Masri H.E. et al., where they analyzed calls by patients taking csDMARDs and bDMARDs to an Australian national medicine call center, patients' most common problem about both csDMARDs and bDMARDs was found to be inadequate information with 44% [22].

Mean years of schooling and expected years of schooling give information about the education level of countries and regions. In their 2016 study, Yeşilyurt M. et al., calculated the average schooling year in Türkiye as 6.51 years while the expected schooling year was 11.03 years [23]. The readability levels of PILs of all drug groups examined in our study are above the actual schooling years in Türkiye. This level should be taken into account while preparing written texts targeting the whole society. The limited level of health HL is one of the important issues in Turkey [24]. Patient readability and comprehensibility of patient information leaflets may also be related to health literacy (HL), comprehensive studies are needed on this subject.

## Conclusion

In conclusion, we determined in our study that on average 11-12 years of education, *i.e.* high school education, is necessary to read and understand the PILs of drugs commonly prescribed in rheumatology practice. Considering that the mean years of schooling in Türkiye is 6.51 years, the said education level is too high. The readability levels of PILs should be in accord with the mean years of schooling in Türkiye. Since patients will thus benefit more and get better information from PILs, we believe that medication errors will be decreased, medication error-related complications may be prevented, or disease exacerbations or activation due to inadequate use may be avoided. We also think that patient adherence to treatment will increase when PILs are understandable by patients. In this study, it was determined that the readability levels of PILs of medications frequently prescribed in daily rheumatology practice were low by patients compared to the average education level in Türkiye. The current readability of the PILs should be adjusted in accordance with the patient's level of understanding and education and arrangements to increase the readability levels of PILs should be introduced.

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## Conflict of interest

There is no conflict of interest.

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