

## Are Consent Forms Used in Cardiology Clinics Easy to Read?

### Kardiyoloji Kliniklerinde Kullanılan Onam Formları Kolay Okunabiliyor mu?

#### ABSTRACT

**Objective:** Informed consent forms are a contract between the patient and the doctor before the medical diagnosis and treatment. It is extremely important that the patient can read and understand such forms. The purpose of the present study was to investigate the readability levels of consent forms recommended by the Turkish Society of Cardiology used in cardiology clinics.

**Methods:** The number of words, syllables, letters, and characters of 20 consent forms that are used in cardiology clinics were calculated. The readability scores were calculated by using the formulas of Ateşman and Bezirci-Yılmaz.

**Results:** It was found that the cardiology consent forms were readable at the 11th or 12th grade according to the Ateşman Index and at the high school level according to the Bezirci-Yılmaz Index.

**Conclusion:** We suggest that the informed consent forms recommended by the Turkish Society of Cardiology must be simplified from the level that requires high school education to the level that requires 6 years of education, which is the average schooling year in Turkey.

**Keywords:** Ateşman, Bezirci-Yılmaz, consent forms, readability

#### ÖZET

**Amaç:** Aydınlatılmış onam formları tıbbi tanı ve tedavi öncesi hasta ile hekim arasında sözleşme niteliğindedir. Hastanın bu formları okuyabilmesi ve anlayabilmesi son derece önemlidir. Biz çalışmamızda kardiyoloji kliniklerinde kullanılan Türk Kardiyoloji Derneği'nin önerdiği onam formlarının okunabilirlik düzeylerini araştırmayı hedefledik.

**Yöntemler:** Kardiyoloji kliniklerinde kullanılan 20 tane onam formlarının kelime sayıları, hece sayıları, harf ve karakter sayıları hesaplandı. Ateşman ve Bezirci-Yılmaz formülleri ile okunabilirlik puanları hesaplandı.

**Bulgular:** Kardiyoloji onam formları Ateşman ölçeğine göre 11. veya 12. sınıf düzeyinde, Bezirci-Yılmaz ölçeğinde ise lise düzeyinde eğitim gerektiren okunabilirlikte olarak saptanmıştır.

**Sonuç:** Türk Kardiyoloji Derneği'nin önerdiği aydınlatılmış onam formlarının lise düzeyi eğitim gerektirecek düzeyden, Türkiye ortalama okullaşma yılı olan 6 yıllık eğitim gerektirecek düzeye sadeleştirilmesini önermekteyiz.

**Anahtar Kelimeler:** Ateşman, Bezirci-Yılmaz, onam formları, okunabilirlik

The value of a text increases to the extent that it can be read and understood. The readability and intelligibility of written texts are extremely important for the authors of these texts and the audience they address. Some indexes, which are proven by scientific studies, evaluate how comprehensible texts are based on their readability.<sup>1</sup>

Health literacy has also become an important problem in our present day. Various texts on the diagnosis and treatment methods to be applied to patients can be easily accessed online.<sup>2</sup> However, the most serious, reliable, and official texts before any procedure are consent forms, which also create legal responsibilities for the patient and the doctor in addition to being informative texts.<sup>3</sup>

#### ORIGINAL ARTICLE KLİNİK ÇALIŞMA

İbrahim Etem Dural, M.D. 

Department of Cardiology,  
Afyonkarahisar Health Science University,  
Afyonkarahisar, Turkey

**Corresponding author:**  
İbrahim Etem Dural  
✉ iedural@hotmail.com

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Cardiology clinics are the places where interventional diagnosis and treatment methods are applied frequently. The premedication and procedures of interventional methods can be difficult for patients to understand, which can cause legal problems in case of any complications.<sup>4</sup> For this reason, it is important for patients to understand the indications of the procedures and the complications of such procedures. Hence, consent forms must be designed in line with the patient population of cardiac disease.<sup>5</sup>

The purpose of the present study was to evaluate the readability levels of consent forms, which are used frequently in cardiology clinics, with the readability indexes that are currently used in our country.

## Methods

The present study had a descriptive design. The consent forms that are recommended by the Turkish Society of Cardiology, which are most used frequently in cardiology clinics, were used in the study as the material. A total of 20 consent forms that were read and signed by patients before diagnosis and treatment methods in cardiology clinics were evaluated by using Ateşman and Yılmaz-Bezirci readability formulas.<sup>6-7</sup>

## Readability Indexes

There are international and national indexes that evaluate the readability of a written text by calculating the number of sentences, words, syllables, letters, and characters. The most commonly used international indexes are Gunning Fog and Flesch-Kincaid Indexes.<sup>8</sup> However, the evaluations of these indexes in Turkish texts do not give the desired results because of the nature of the languages. Ateşman and Bezirci-Yılmaz Indexes used in national studies are more suitable for Turkish texts.<sup>9-11</sup>

A formula was developed according to the number of words and syllables in the text in the Bezirci-Yılmaz Readability Index as follows:

$$RS = \sqrt{AVC} \times ((H3 \times 0.84) + (H4 \times 1.5) + (H5 \times 3.5) + (H6 \times 26.25))$$

where RS is the readability score, AVC is the average word count, H3 is the average number of 3-syllable words, H4 is the average number of 4-syllable words, H5 is the average number of 5-syllable words, and H6 is the average number of words with 6 or more syllables.

The education level corresponding to the readability score is given in Table 1.<sup>7</sup>

The calculation was made by taking the first 100 words of the text over the formula for the Ateşman Readability Index calculation.

## ABBREVIATIONS

AVC	Average word count
CRT	Cardiac resynchronization therapy
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 words with 6 or more syllables
ICD	Implantable cardioverter defibrillator
RS	Readability score

**Table 1. Education Levels Corresponding to the Score/Class Obtained with the Bezirci-Yılmaz Readability Formula<sup>7</sup>**

Score	Education Levels
1-8	Primary education
9-12	Secondary education (high school)
12-16	Undergraduate education
16+	Academic level education

**Table 2. Education Levels Corresponding to the Score Obtained with the Ateşman Readability Formula<sup>6</sup>**

Score	Education Levels
90-100	Readable by anyone with 4th grade education of primary school and below
80-89	Readable by anyone with 5th or 6th grade education
70-79	Readable by anyone with 7th or 8th grade education
60-69	Readable by anyone with 9th or 10th grade education
50-59	Readable by anyone with 11th or 12th grade education
40-49	Readable by anyone with 12th or 13th grade education
30-39	Readable by anyone with undergraduate level education
≤29	Readable by anyone with postgraduate degree education

According to this formula, the readability level of a text is determined to be easier as the readability level approaches 100 and more difficult as it approaches 0.

$$RS = 198.825 - (40.175 \cdot X1) - (2.610 \cdot X2)$$

where RS is the readability score, X1 is the number of syllables/word count, and X2 is the word count/sentence count.

The evaluation of the results between 0 and 100 according to the education level is given in Table 2.<sup>6</sup>

The formulas were calculated with the computer program that was developed by Bezirci-Yılmaz.

## Ethics Committee Approval

The study protocol was approved by the Afyonkarahisar Health Sciences University Ethics Committee (date: March 4, 2022, no: 2022/3)

## Results

According to the readability indexes, the scores of the consent forms are given in Table 3.

The readability score of the 18 consent forms in the Ateşman Index was between 50 and 59, which were the ranges of scores that required 11th or 12th grade education. The readability of the Coronary Angiography Consent Form required 13th or 15th grade level of education, and the Supra Ventricular

**Table 3. Results of Consent Forms According to Readability Indexes**

	Gunning Fog	Flesch-Kincaid	Ateşman	Bezirci-Yılmaz
Coronary angiography	17.59	24.12	47.66	14.09
Coronary intervention	15.23	21.57	58.60	10.66
Carotid angiography	16.97	23.12	53.10	11.55
Carotid intervention	16.20	22.35	55.18	11.61
Peripheral artery intervention	17.35	22.49	55.55	10.85
Transesophageal echocardiography	17.03	23.10	52.64	13.54
Pericardiocentesis	17.56	23.73	51.02	14.56
Cardioversion	16.50	21.83	59.51	9.24
Electrophysiological study	16.42	22.56	55.30	12.64
Supraventricular tachycardia ablation	16.21	21.27	60.95	10.01
Ventricular tachycardia ablation	17.18	21.94	57.52	11.07
Atrial fibrillation ablation	16.57	21.56	59.52	9.90
Pacemaker implantation	16.29	21.88	57.25	10.92
ICD implantation	16.42	21.91	58.51	10.17
CRT implantation	17.23	22.59	54.67	11.13
Atrial septal defect closure	16.60	22.52	54.91	12.04
Endomyocardial biopsy	17.70	24.36	49.19	13.32
Transcatheter aortic valve replacement	17.09	22.75	53.07	13.59
Balloon mitral valvuloplasty	15.90	21.46	59.64	9.97
Carillon	17.16	22.13	56.28	11.69

ICD, implantable cardioverter defibrillator; CRT, cardiac resynchronization therapy.

Tachycardia Ablation Consent Form required 9th or 10th grade level of education.

A total of 13 consent forms required high school education, and 7 consent forms required undergraduate education for their readability according to the Bezirci-Yılmaz Index.

The average scores of the consent forms according to the readability indexes, the number of words, sentences, syllables, characters, and letters are given in Table 4.

To be able to read consent forms, 11th or 12th grade education was required on average according to the Ateşman Index,

**Table 4. Average Character Counts and Readability Scores of Consent Forms**

Number of sentences	110.55
Number of words	1186.55
Number of syllables	3401.1
Number of letters	7984.45
Number of characters	9424.3
Number of polysyllable words ( $\geq 4$ )	369.2
Gunning fog Index	16.76
Flesch-kincaid Index	22.46
Ateşman Index	55.50
Bezirci-Yılmaz Index	11.62

and high school education was required according to the Bezirci-Yılmaz Index. Although Gunning Fog and Flesch-Kincaid Indexes were not fully compatible with Turkish, their readability levels were scored in a way that could be interpreted as very difficult.

### Discussion

Informed consent forms are a legal contract in patient-doctor relations, and for this reason, they are extremely important for both the patient and the doctor. Consent forms are a written confirmation of verbal trust in the patient-doctor relationship. They are also a declaration of the principles of Medical Law and Medical Ethics in the diagnosis and treatment method to be applied by the doctor. Doctors have to follow the Law and Ethics of Medicine when they apply the current evidence-based medical methods.<sup>12</sup>

Cardiology doctors must have patients sign an informed consent form before interventional procedures as all doctors do. This was enacted in the Constitution of the Republic of Turkey with the Law on the Practice of Medicine and Medical Sciences. For this reason, patients who apply to cardiology clinics must understand the consent forms well. Therefore, there is a need for consent forms to explain the necessities of the procedure, possible benefits, and risks of complications.<sup>13</sup>

Most medico-legal problems are caused by complications. Patients must be informed well about complications and risks. A complication developing after a procedure causes malpractice complaints if it is not understood well.<sup>14</sup>

Cardiology clinics are places where advanced invasive procedures are performed. It is not easy to explain the procedure to be used in diagnosis and treatment to patients in detail. It is necessary to use plain language by considering the sociocultural status of the patient. Consent forms must also be legible with these qualifications. The readability of written texts can be evaluated objectively. Assessing the readability of documents that are the most important on a legal basis in the field of health, for example, consent forms, will shed light on the authors of these documents.<sup>15</sup>

The term "readability" was first introduced in the United States in 2004. Since then, there have been more than 200 readability indexes for English, which is the most frequently used language in medical literature.<sup>16</sup> The most widely used Flesch-Kincaid Index was used in medical texts.<sup>17</sup> In clinical studies, consent forms were evaluated with these indexes. Ateşman and Bezirci-Yılmaz Indexes, which are used for Turkish texts, were also used in medical texts.<sup>11</sup>

The written text is scored according to the ratio of the number of syllables to the number of words and the number of words to the number of sentences in the Ateşman Index.<sup>6</sup> The syllable counts of the words in the texts were formulated in the Bezirci-Yılmaz Index.<sup>7</sup> The results of these indexes, which were created with the same logic as the English formulas, were made more suitable for the Turkish education system.

In recent years, readability indexes have also been the subject of research for Turkish medical texts. Prospectuses, public health information texts, and consent forms were evaluated for readability.<sup>12-19</sup> The most important studies are the evaluation of consent forms in terms of legal responsibility.

There are various studies conducted in our country on consent forms. To the best of our knowledge, the first study on consent forms was the study by Boztaş et al.<sup>12</sup> In the study in which the readability level of consent forms used before anesthesia was found to be 33.2 according to the Ateşman Index, the authors suggested simplification of the consent forms because this level requires an undergraduate education.<sup>12</sup> In our study, the readability level of consent forms used in cardiology is 55.50. We showed that consent forms, which we found to be easier to read than anesthesia consent forms, still require high school education.

There are also studies evaluating the readability of consent forms used in internal diseases, emergency services, urology clinics, and ophthalmology clinics in our country.<sup>11-22</sup> And the common point of all these studies is that readability levels of consent forms require at least high school education according to Ateşman and Bezirci-Yılmaz Indexes. In our study, we also determined that consent forms used before cardiac interventions require at least high school education to be easily read.

We also concluded that the readability of consent forms is unrelated to the complexity of the procedure. According to the Ateşman Index, the Coronary Angiography Consent Form is the most difficult to read, while the Supraventricular Tachycardia Ablation Consent Form is the easiest to read. According to the Bezirci-Yılmaz Index, the pericardiocentesis consent form is the most difficult to read, while the cardioversion consent form is the

easiest to read. However, although there is a numerical difference in the readability indexes between the consent forms, we have seen that they require almost the same education level.

In the study, it was found that the readability of the consent forms required at least high school education. It was shown that a patient with at least 11 years of education can easily read and understand consent forms in both readability indexes. In the study of Eltoria et al<sup>23</sup> conducted in the United States, the readable scores of consent forms used in invasive interventions, which required 15 years of education, were determined. The average year of education in the United States was evaluated as 8 years, and it was recommended that the consent forms be written in legibility that required 6 years of education.

The average schooling year and expected schooling year, also used in the United Nations Development Program, provide information on the education levels of countries and regions. In a study that was conducted by Yeşilyurt et al<sup>24</sup> in 2016, Turkey's average schooling year was reported as 6.51 years and the expected schooling year as 11.03. In the present study, an education level was required in the expected schooling year for the readability of consent forms.

When the fact that Turkey's average schooling year is 6.5 years is considered, consent forms used in the cardiology clinic must be at a readability level that requires a maximum of 6 years of education. The fact that consent forms are readable and understandable by the general patient population will contribute to increased patient confidence and strengthen the doctor's medical and legal aspects.

## Conclusion

It was shown that the readability levels of 20 informed consent forms that were recommended by the Turkish Society of Cardiology used in cardiology clinics required high school education on average. This level is above Turkey's average schooling year. The readability of consent forms at the 6-year education level will enable them to be used more efficiently in this respect.

**Ethics Committee Approval:** Ethical committee approval was received from the Ethics Committee of Afyonkarahisar Health Sciences University (Approval no: 2022/3, date: March 4, 2022).

**Informed Consent:** N/A.

**Peer-review:** Externally peer-reviewed.

**Declaration of Interests:** The author declare that he has no competing interest.

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