Original Article

HEALTH SCIENCES
MEDICINE

DOI: 10.32322/jhsm.1325569
J Health Sci Med. 2023;6(5):860-864

Evaluation of the readability of consent forms used in cardiovascular surgery clinics

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Cite this article as: Kaya İÇ. Evaluation of the readability of consent forms used in cardiovascular surgery clinics. *J Health Sci Med.* 2023;6(5):860-864.

Received: 10.07.2023 ◆ **Accepted**: 28.07.2023 ◆ **Published**: 28.09.2023

ABSTRACT

Aims: The readability of the informed consent forms, which are a power of attorney agreement between the physician and the patient, is very important especially in clinics where high-risk procedures such as cardiovascular surgery are performed. In this study, we aimed to determine the readability levels of consent forms, which are frequently used in cardiovascular surgery clinics, according to accepted scales.

Methods: The readability level of the 15 patient consent forms recommended by the Turkish Society of Cardiovascular Surgery to its members; word counts, syllable counts, letter and character counts were calculated using Ateşman and Bezirci-Yılmaz formulas.

Results: Consent forms included in the study were found to be readable at the 11-12th grade level according to the Ateşman scale and at the high school level in the Bezirci-Yılmaz scale. These texts have also been studied at international scales and it has been determined that they are at the level of readability that requires undergraduate education.

Conclusion: Research and data from the Turkish Statistical Institute show that the average year of schooling in our country is 6.5, and the ratio of high school graduates or equivalent to the entire population is 22.3%. We advocate simplifying the informed consent forms recommended by the Turkish Society of Cardiovascular Surgery, from the level that requires high school education to the 6-year education level, which is the average schooling year in Turkey.

Keywords: Informed consent, readability, comprehension

INTRODUCTION

It is very important to inform patients and their relatives about possible complications that may develop after operations in cardiovascular surgery clinics because of the high mortality and morbidity rates of the operations performed. Informed Consent (IC) is accepted as an important element for the medical intervention to be accepted as an intervention in line with laws and medical ethics because of respect for the patient's right to autonomy.[1] In medical interventions, the consent of the patient is an important reason for compliance with privacy law and criminal law. However, the existence of certain elements is important for the consent to be valid. The most important one is the "obligation to inform", which allows the patient to know what s/he consents to, which must be fulfilled.[2] Right at this point, it is necessary to emphasize the importance of the readability level of the informed consent forms, which have the nature of a power of attorney agreement between the physician and the patient.

The readability concept emerged in the USA at the beginning of the 19th century.[3] It is often confused with the concept of legibility. Legibility is determined by characteristics such as the font of the text and the shape of the page. On the other hand, readability is the knowledge of whether a text in any language can be easily followed by the reader(s).[4] In short, readability can be expressed as the level of understanding of a text.

In this study, the purpose was to evaluate the readability levels of informed consent forms, which are used widely in cardiovascular surgery clinics, with the readability scales used in our country and the international literature.

METHODS

The study was carried out with the permission Eskişehir City Hospital Non-invasive Clinical Researches Ethics Committee (Date: 15.02.2023, Decision No: ESH/GOEK

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2023/8). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

A total of 15 informed consent forms,[5] which are frequently used in cardiovascular surgery clinics in our country and recommended to the members of the Turkish Society of Cardiovascular Surgery (TSCS), taken from the official site of TSCS were included in the study. The consent forms were evaluated using the Ateşman and Yılmaz-Bezirci scales, which are frequently used for Turkish texts, and the Fresch-Kincaid, Gunning Fog, Automated Readability Index (ARI) scales, which are frequently used in international studies.

Readability Scales

Readability studies first appeared with formulas created according to the word and sentence structure of English and developed in different countries. The readability formulas accepted in the international literature are Flesch-Kincaid (1975), Gunning Difficulty Indicator (1952), and Automated Readability Index (ARI) (1967). After these studies, the study of creating a formula to measure the readability difficulty of Turkish for the first time started with the adaptation of the constants in Flesch's Formula according to the characteristics of Turkish by Ateşman (1997). Bezirci and Yılmaz (2010) analyzed five different studies for English and developed a formula for Turkish that they named "New Readability Value".[6]

The calculation was made by taking the first 100 words of the text over the formula in Atesman Readability Scale. According to this formula, the readability level of a text is determined to be easier as it approaches 100, and more difficult as the readability level approaches 0.[7]

$$RS=198.825-(40.175.X1)-(2.610.X2)$$

RS: Readability Score
X1: Number of syllables/word count
X2: Word count/sentence count

The evaluation of the results between 0-100 according to the level of education is shown in Table 1.

Table 1. Education levels corresponding to the scores obtained by Ateşman readability formula[7]

Scores	Education Levels
90-100	It can be read by anyone with an education level of 4th grade and below in primary school.
80-89	It can be read by anyone with a 5-6th grade level education.
70-79	It can be read by anyone with a 7-8th grade level education.
60-69	It can be read by anyone with a 9-10th grade level education.
50-59	It can be read by anyone with a 11-12th grade level education.
40-49	It can be read by anyone with a 12-13th grade level education.
30-39	It can be read by those who have studied undergraduate.
≤29	It can be read by those with a postgraduate education.

The following formula was developed according to the number of words and syllables in the text in the Bezirci-Yılmaz Readability Index.

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

RS refers to readability score, AVC refers to the average number of words, H3 refers to the average number of 3-syllable words, H4 refers to the average number of 4-syllable words, H5 refers to average 5-syllable words, and H6 refers to the average number of words with 6 or more syllables. The scores and education levels according to Bezirci-Yılmaz Readability Scale are shown in Table 2.[8]

Table 2. Education levels corresponding to the scores obtained from the Bezirci-Yılmaz Readability Scale[8]

Scores	Education Levels
1-8	Primary and secondary school
9-12	High school
12-16	Undergraduate
16+	Postgraduate

The computer program developed by Bezirci-Yılmaz was used to calculate the formulas.

$$206.835 - 1.015\left(\frac{\text{total words}}{\text{total sentences}}\right) - 84.6\left(\frac{\text{total syllables}}{\text{total words}}\right)$$

In the Flesch reading-ease test, higher scores indicate material that is easier to read; lower numbers mark passages that are more difficult to read. The formula for the Flesch reading-ease score (FRES) test is:

The Gunning Fog Index Readability Formula, or simply called FOG Index, is attributed to American textbook publisher, Robert Gunning, who was a graduate from Ohio State University.

Grade level=0.4 (ASL + PHW)

ASL=average sentence length (i.e., number of words divided by the number of sentences) PHW=Percentage of hard words[19]

The automated readability index (ARI) is a readability test for English texts, designed to gauge the understandability of a text. Like the Flesch-Kincaid grade level, Gunning fog index, SMOG index, Fry readability formula, and Coleman-Liau index, it produces an approximate representation of the US grade level needed to comprehend the text.[20]

The formula for calculating the automated readability index is given below:

$$4.71\left(\frac{\text{characters}}{\text{words}}\right) + 0.5\left(\frac{\text{words}}{\text{sentences}}\right) - 21.43$$

RESULTS

The scores of all consent forms that were included in the study according to the readability scales are given in Table 3. The endovascular procedures consent form was determined at the readability level that required undergraduate education according to both Ateşman and Bezirci-Yılmaz Scales. It is noteworthy that this value is the most difficult to read among all consent forms.

Table 4 shows the mean scores of the forms on each scale and the level of education that these scores correspond to in the scale. The mean scores of the consent forms on the Ateşman Scale require education at 11-12th grade and are 57.5. According to the Bezirci-Yılmaz Scale, they have an average of 9.15 points and are in a class that requires a high school education. Although the ARI, Flesch-Kincaid, and Fog Scales are considered to be not suitable for Turkish, they were studied for comparison purposes and their readability levels were found to be very difficult and at the undergraduate level in correlation with local scales.

Table 4. Average scores and education levels according to readability scales

	Average scores	Education levels
Ateşman	57,53	11-12th grade level education
Bezirci-Yılmaz	9,15	High school
Gunning Fog	16,84	College senior
Flesch-Kincaid	14,89	College graduate
ARI	22,74	College student

ARI: Automated Readability Index

DISCUSSION

This increased interest in the readability levels of the texts is associated with the concept of moral autonomy, which enables patients to make decisions about themselves. Previous studies conducted to develop patient-centered texts are essential in the new model of clinical relationships based on the "patient-first" concept. Laws regulating human rights in healthcare allow patients to play greater roles in making decisions that affect them. Because, as well as the knowledge and technical competence, healthcare professionals must help patients understand their situation so that they can make decisions. Essentially, the information given must be comprehensible as well as accurate, and sufficient to help patients make decisions.[9,18]

In their study, Yesilyurt et al.[10] introduced the concept of "expected and current schooling year" in 2016, and according to 2016 data, they declared the current schooling year of Turkey as 6.15 and the expected schooling year as 11.03. According to the data of the Turkish Statistical Institute (TUIK) for December 2022, high school graduates or an equivalent school currently constitute 22.3% of the entire population in our country. The rate of illiterate and primary and secondary school graduates is 43% of the entire population.[11]

Although studies conducted on the evaluation of medical texts according to readability criteria have attracted attention in recent years, there are very few studies on cardiovascular operations. As far as we know, the present study is the first for Turkish consent forms.

Table 3. Scores of patient consent forms according to readability scales

	Ateşman	Bezirci-Yılmaz	Gunning Fog	Flesch-Kincaid	ARI
Abdominal aortic, aortailiac and aortafemoral surgery	57,17	9,4	17,45	22,88	14,8
Aortic valve surgery	62,04	7,92	16,06	21,73	13,81
Ascending/Arcus aortic surgery	52,11	10,69	17,42	23,74	15,97
Ascending/descending aortic surgery	57,7	9,3	16,72	22,47	14,83
Pediatric heart surgery	66,59	5,88	14,67	21,21	13,03
Embolectomy	57,71	9,08	17,28	22,67	14,7
Endovascular procedures	39,83	15,63	19,75	26,17	19
Femoropopliteal bypass	62,51	6,93	14,65	22,04	13,98
Intracardiac tumor surgery	61,51	8	16,22	21,89	13,95
Carotid endarterectomy	60,21	8,4	16,66	22,09	14,24
Coronary artery bypass grafting	55,47	9,34	17,32	23,46	15,67
Arteriovenous fistula surgery	58,65	8,52	17,17	22,58	14,7
Mitral valve surgery	61,52	8,02	16,28	21,86	13,96
Peripheral vascular interventions	60	8,63	17,03	22,11	14,27
Thoracic/thoracoabdominal aortic replacement	50,02	11,61	18,03	24,28	16,46

ARI: Automated Readability Index

In the present study, the average education level of the patient information and consent forms recommended by the Turkish Society of Cardiovascular Surgery is 11-12 according to the Ateşman Scale. According to Bezirci-Yılmaz Scale, it was determined that the grade was at least high school level. These scales were also compared with international scales and it was found that the readability level in them is at the undergraduate level.

Similarly, Dural et al.[12] conducted a study on consent forms used in cardiology clinics in 2022 and reported that the readability level of these forms was at the high school level, which is similar to our results. Endovascular interventions consent form was found to be the most difficult to read in the present study and required undergraduate education according to both Ateşman and Bezirci-Yılmaz. In Dural's study, consent for coronary angiography was 12-13 according to Ateşman. It was grade level and had the lowest score (hardest). But no consent form was scored at the undergraduate level.

San Norberto et al.[13] investigated the readability levels of 504 consent forms in different branches of medicine with 5 different readability scales and reported that the readability of consent forms of Spanish surgical specialties was beyond the average education level of the population as a whole. In the same study, it is valuable to say that the only national scientific community that developed consent forms with appropriate readability was Angiology and Vascular Surgery.

In Fischer's study that was published in 2021, 75 separate consent forms were evaluated with 3 scales, one of which was Flesch-Kincaid, and it was found that 2 out of 3 of them did not meet the readability standards accepted in South Africa. The biggest limitation of the studies that were conducted in regions where English was not the mother tongue, including this study, was that these studies were conducted using standard programs without adapting the readability scales to that language because of the nature of the languages.[14,15] It is possible to explain this most simply, although the number of syllables in our language is calculated by the number of vowels in the word, this is not the case in English.[16,17] These are also limitations of our study. For this reason, it is important that our study was conducted with two different scales that were adapted to Turkish.

Of course, patients are not informed only with consent forms before the surgery. Aside from written consent forms, they can have more detailed verbal information from the physicians, and they can even benefit from open sources themselves. However, when emphasizing the importance of readability level, Temur argued that readability and intelligibility were different concepts and both must be evaluated.[15] It can be said that these were the limitations of our study.

CONCLUSION

A total of 15 informed consent forms recommended by the Turkish Society of Cardiovascular Surgery and frequently used in cardiovascular surgery clinics were analyzed by using national and international readability scales, and the average readability education level was found to be 11-12th grade (high school) levels. The current schooling year is 6.5 years in our country. According to TUIK data for 2021, approximately 30% of the population was primary school graduates and 20% was secondary school graduates. Having sufficient and satisfactory information on possible complications before surgery will minimize the legal and moral problems between the patient and the physician in case of possible negativities. For this reason, we advocate that the readability levels of patient information and consent forms must be revised and updated to the 6th-grade level.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission Eskişehir City Hospital Non-invasive Clinical Researches Ethics Committee (Date: 15.02.2023, Decision No: ESH/GOEK 2023/8).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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