










Evaluation of the readability of informed consent forms used in urology: Is there a difference between open, endoscopic, and laparoscopic surgery?

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ABSTRACT

Objective: The aim of this study is to evaluate the readability levels of informed consent forms used in Turkey before urological surgery and to compare the readability levels of open, endoscopic, and laparoscopic surgical informed consent forms.

Material and Methods: A total of 529 informed consent forms used for urological open, endoscopic, and laparoscopic surgical procedures were collected from different hospitals in Turkey. Evaluating informed consent forms that have exactly the same text only once, a total of 69 consent forms were evaluated. The Gunning Fog Index and Flesch–Kincaid test measuring the general readability level were used to calculate the readability level of informed consent forms in addition to the Ateşman and Bezirci–Yılmaz formulas defined to determine the readability level of Turkish texts. Informed consent forms were evaluated and divided into three groups as open, endoscopic, and laparoscopic surgery forms, depending on their content.

Results: Among 69 informed consent forms evaluated, 35 were open, 19 were endoscopic, and 15 were laparoscopic surgery consent forms. The readability level of all informed consent forms was detected as average according to the Ateşman formula, very difficult according to the Flesch–Kincaid test, difficult according to the Gunning Fog Index, and at the high school education level according to the Bezirci–Yılmaz formula. A statistical evaluation of the three groups did not show a significant difference in the readability level.

Conclusion: In this study, it was detected that the informed consent form readability levels used for urological surgical procedures in our country were rather low. We think that the cooperation of the concerned institutions is required for the revision of the consent information texts available and the improvement of the texts according to the strategies recommended.

Keywords: Informed consent forms, readability, understandability, urological surgery

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INTRODUCTION

Informed consent means the authorization given to the health professional for the diagnosis or treatment interventions planned with the patient's consent. Informed consent forms (ICF), being an inseparable constituent of the consent phase, are used to help the patients during the treatment phase by explaining the indications, advantages, and possible risks of medical applications (1). It was also shown that these texts may be effective in solving problems in the treatment phase with advantages such as providing the patient–doctor communication and making the agreement of the patient to treatment easier (2, 3). But as the value of information is limited with the comprehension ability of the patients, the “readability” and “understandability” of information are as important as its reliability and currency.

Presenting some quantitative data on texts, readability provides information on whether the text is easily understandable by the reader at a certain level through the characteristics of the syllables, words, and sentences in that language. Factors influencing readability are the average word length, word frequency, multisyllabic words, average sentence length, ambiguous word number, and average syllable number. The sentence readability of decreases as the number of words in a sentence increase. Readability formulas were developed using criteria such as the length of words and sentences and the word syllable number in readability evaluation. There are many formulas developed for readability analysis (4-9).

The Ateşman and Bezirci–Yılmaz formulas (6, 7) defined to determine the readability level of Turkish texts and Gunning Fog Index and Flesch–Kincaid test measuring the general readability level are the most common readability formulas used (8, 9). In a research conducted in Turkey, it was found that 64.6% of the public had inadequate health literacy (5).

The aim of this study is to evaluate the readability levels of ICFs used in our country before urological surgery and to compare the readability levels of ICF specifically prepared for open, endoscopic, and laparoscopic surgery.

MATERIAL AND METHODS

This research was conducted according to the principles of the World Medical Association's Declaration of Helsinki. Since there were no human participants in this study, it was not necessary to obtain ICF.

A total of 529 ICFs used for urological open, endoscopic, and laparoscopic surgical procedures were collected from different hospitals in Turkey. Evaluating ICFs that have exactly same text only once, a total of 69 consent forms were evaluated for the sentence number, word number, letter number, character number, syllable number, and words with an average syllable number of four and above.

The informative text available in these consent forms was copied and transferred to Microsoft Word (Microsoft, Redmond, WA) program and was calculated manually with Microsoft Excel (Microsoft, Redmond, WA) program. The Ateşman and Bezirci-Yılmaz formulas (6, 7) for determining the readability level of Turkish texts and the Gunning Fog Index and Flesch-Kincaid (8, 9) test for measuring the general readability level were used for calculating the readability level of ICF.

Ateşman readability formula (Ateşman readability formula, Ankara, Turkey)

The Ateşman readability formula is a formula based on the length of words and sentences.

The readability score is formulated as $198.825 - 40.175 \times (\text{total syllables} / \text{total words}) - 2.610 \times (\text{total words} / \text{total sentences})$. It is understood that the readability level of a text is considered easier when it is closer to 100 and harder when it is closer to 0, according to the Ateşman formula.

Table 1. Readability intervals of the readability formulas used in the study		
Ateşman Value	Readability Interval	
90–100	Very easy	
70–89	Easy	
50–69	Average difficulty	
30–49	Difficult	
1–29	Very difficult	
Bezirci-Yılmaz Value	Readability Interval According to the Education Level	
1–8	Elementary school	
9–12	High school	
12–16	Bachelor's degree	
>16	Academic	
Gunning Fog Index Value	Readability Interval	
8–10	Easy	
>11	Difficult	
Flesch-Kincaid Grade Level	Numeric Level of the Text	Readability Interval
5	90–100	Very easy
6	80–90	Easy
7	70–80	Quite easy
8–9	60–70	Standard
10–11	50–60	Rather difficult
13–16	30–50	Difficult
Adults	0–30	Very difficult

Bezirci-Yılmaz readability formula (Bezirci-Yılmaz readability formula, Ankara, Turkey)

The Bezirci-Yılmaz readability formula was developed based on the sentence length and syllable number in words, characteristics of different formulas developed until today, and the statistical characteristics of the Turkish language. According to this formula, the readability difficulty of the text increases when the sentences in the text are longer. Similarly, an increase of the syllable number in a word makes the readability of that word and the sentences harder most of the time.

$$\sqrt{AWN \times ((S3 \times 0.84) + (S4 \times 1.5) + (S5 \times 3.5) + (S6 \times 6.26.25))}$$

AWN: Average word number; S3: Number of words with an average of three syllables; S4: Number of words with an average of four syllables; S5: Number of words with an average of five syllables; S6: Number of words with an average of six or more syllables

The result acquired from this formula explains which class level a text addresses to according to the education system in our country. The education system shows the elementary school education level for Grades 1–8, secondary (high) school education for Grades 9–12, bachelor's degree for Grades 12–16, and academic education level for Grades 16 and above.

Flesch-Kincaid test (Flesch-Kincaid test, Columbia, USA)

The length of the words and sentences is determined.

$$\text{Readability} = (0.39 \times \text{sentence length}) + (1.18 \times \text{word length}) - 15.59$$

$$\text{World length} = \text{syllable number} / \text{word number}$$

$$\text{Sentence length} = \text{word number} / \text{sentence number}$$

The syllable number is divided with the word number for the word length, and the word number is divided with the sentence number for sentence length. The text is evaluated as easy when the syllable number of each word is closer to 1 and as difficult when the syllable number rises up to 10. The same operation is valid for the sentence. The text is evaluated as easy when the word number decreases to 1 and as difficult when it is more than 10.

Gunning Fog Index (Gunning Fog Index formula, New York, USA)

There are two important aspects of the Gunning Fog Index. These are words containing three or more syllables and the average number of words used in sentences.

$$\text{Fog Index} = 0.4 \times (\text{word rate with three syllables} + \text{average number of words})$$

$$\text{Word rate with three syllables} = (\text{number of words with three or more syllables} / \text{remaining number of words}) \times 100$$

$$\text{Average number of words} = \text{word number} / \text{sentence number}$$

It is an easy text if the result is between 8 and 10 and a difficult text if the result is above 11.

The readability intervals of the readability formulas used in the study are available in Table 1.

Informed consent forms were separated into three groups as open (Group 1), laparoscopic (Group 2), and endoscopic (Group 3) surgery according to their content. The readability levels were compared with the Ateşman, Bezirci-Yılmaz, Gunning Fog, and Flesch-Kincaid formulas and the sentence number, word number, letter number, character number, syllable number, and average number of words with four and more syllables.

Statistical Analysis

The SPSS 20.0 (IBM Corp.; Armonk, NY, USA) program was used for statistical evaluation. For the comparison of the groups, T-test and Mann-Whitney U test were used for binary group analyses, and the Kruskal-Wallis test was used for triple groups analyses. $p < 0.05$ was regarded as significant for all examinations.

RESULTS

Among 69 ICFs evaluated, 35 were open (Group 1), 15 were laparoscopic (Group 2), and 19 were endoscopic surgery (Group 3) consent forms. No significant difference was observed in the sentence number, word number, letter number, character number, syllable number, and words with an average syllable number of four and above among the consent forms. Among the three groups and among the groups in binary statistical evaluation, no significant difference was detected in readability level among the groups.

Readability level of all consent forms was detected as average according to the Ateşman formula, very difficult according to Flesch-Kincaid test, difficult according to the Gunning Fog Index, and at high school education level according to the Bezirci-Yılmaz formula. Numeric and statistical values among the groups are available in Table 2.

DISCUSSION

Informed consent is one of the most important aspects of ethical medical practice. In legal terms, making an intervention without informed consent may mean negligence or malpractice and may lead to a legal action, maltreatment, and even an attack against the doctor. Informed consent allows the patient

to understand the risks and benefits of all interventions and provides the voluntary consent of patients to be able to continue the procedure. A consent form through which the patients can completely understand the process to be made can be called the ideal informed consent. Ethically, to be able to make a conscious decision, it is very important for the patient to understand the recommended procedure (10, 11). Also, the increasing tendency of health insurance costs and malpractice cases, especially for the surgeons and doctors making invasive interventions, makes the readability and understandability of ICFs even more important (11-13).

It is estimated that the patient level of understanding during the informed consent phase is better than it is actually reported (14). But Crepeau et al. (15) found the understanding and recalling of the patients for surgical consent form to be unexpectedly low. As the average readability level of adults in the United States is at the eighth-grade level, the National Institutes of Health and the American Medical Association suggest that the readability of patient materials should be lower than or at the sixth-grade reading level (16-18).

While the average education level of the whole population over 15 years of age is reported as 7.18 years in Turkey according to 2010 data, the average education level of only the females over 15 years of age is reported as 6.33 years (19). Also, according to a research made in 2014, it was found that two-thirds of the population in Turkey has an inadequate level of health literacy (5). So, it is considered that easy readability of ICFs in Turkey would increase the clarity of the procedure to be applied.

Readability levels of ICFs were measured in different countries for different medical branches before. According to Mariscal-Crespo et al. (20) ICFs used in public hospitals were analyzed globally in Spain, and it was shown that 62.4% had "somewhat difficult," 23.4% had "normal," and 13.4% had "very difficult" readability. The ICF readability values among the branches were compared in another study, and it was reported that

Table 2. Numeric and statistical values among the groups

	Total	Group 1 Open	Group 2 Laparoscopic	Group 3 Endoscopic	Group 1, 2, 3 p*	Group 1-2 p+	Group 1-3 p+	Group 2-3 p+
Informed consent form number	69	35	15	19				
Sentence number	121.9±34.2	119.9±33	133±39.1	117±31	0.24	0.39	0.4	0.86
Word number	1093±272	1033.2±215	1251.3±333.9	1078.3±278	0.07	0.06	0.33	0.36
Letter number	7445.3±1951	7129.1±1608	8313.1±2603	7342.6±1843	0.25	0.054	0.61	0.22
Character number	9294±2293	8870.6±1901	10397±2900	9202.3±2321	0.14	0.064	0.45	0.35
Syllables number	3245.7±844	3101.4±704	3643±1096	3197.9±803	0.23	0.06	0.6	0.24
Words with an average syllable number of four and above	364.9±113	350.1±97	410.2±162	356.4±88.7	0.26	0.059	0.7	0.07
Flesch-Kincaid	23.1±2	23.18±1.6	22.9±3.3	23.12±1.3	0.35	0.06	0.82	0.08
Gunning Fog	17.05±1.7	16.9±1.6	17.2±2.3	17±1.5	0.4	0.13	0.11	0.24
Ateşman	55.1±7.3	55.5±7	54.5±9.7	55±6.1	0.47	0.2	0.16	0.22
Bezirci-Yılmaz	9.68±1.8	9.43±1.8	9.9±2.2	9.91±1.6	0.17	0.31	0.31	0.39

*Kruskal-Wallis test; +Mann-Whitney U test
 Datas are presented as mean ± SD

urology ICFs were at a “very and somewhat difficult” interval (21). We think that this situation may be related to the fact that urological operations especially include endoscopic and laparoscopic surgeries, and ICFs containing the details of different special techniques used in these cases cannot be prepared at a level understandable by the patients. So, we compared the readability levels of open, endoscopic, and laparoscopic consent forms in our study. Although no significant difference was detected between the readability levels of all three surgery groups, we detected that the average of sentence, word, syllable, and number of words with four and more syllables was higher for laparoscopic surgeries.

Gargoum and Keeffe (22) evaluated the information forms used for endoscopic interventions in Ireland and reported that only 62% of the forms were easy to read, and 57% were at the reading level of 13–15 years of age. In a study made in the United States, it was reported that the invasive operation ICFs were written at an average of 15th grade level (i.e., third year of college) (23). Boztaş et al. evaluated the ICFs used before anesthesia in Turkey and reported that these had low-to-very low readability levels (4). Şahin et al. reported that 41.5% of the patients who underwent orthopedic surgery after taking ICF in Turkey did not remember potential complications, and only 29.6% of the patients completely read the ICFs (24).

Difficult readability level can be one of the reasons for not reading ICFs completely. In our study, it was detected that the urological ICFs had a different readability level and were understandable at the high school education level. This condition is in line with studies made in different branches in many countries. So, the things to be done so that ICFs can be more readable and understandable should be discussed.

Borello et al. (1) prepared ICFs that were made easier to comprehend with marked texts and diagrams for laparoscopic cholecystectomy and reported that these forms are easier to understand and remember. Shukla et al. (25) reported that the cataract surgery ICFs at the second-grade reading level and video support are easier to understand.

To increase the readability level of ICFs, we recommend decreasing the number of multisyllabic words, sentences, and words, to form the document by words in an understandable level for the patient, to minimize the words with a medical content that cannot be understood by the patient, and to enrich them with visual information such as videos and diagrams. Also, the patients may have acquired information on the subjects on the surgical procedure themselves (especially through the internet), which may not actually be correct, and patients with a low educational level may feel ashamed to ask the questions for explanation. Thus, the doctor has to be open in the evaluation phase of ICFs, give opportunity to the patients to ask questions, and should spare adequate time for the patient. Additionally, giving permission to an individual such as a relative or friend whom the patient trusts during the informed consent phase may help the patient to understand the ICFs readability and the procedure to be applied, and it may provide emotional support. We think that the application of all these strategies would let the patients understand the procedure and increase the recall rates of the procedure risks.

CONCLUSION

A readability level of the urology ICFs used in our country was detected to be low and difficult in this study. Also, a significant difference was not detected in the readability among the open, endoscopic, and laparoscopic surgery ICFs. We think that attention should be paid to this subject, which is both medically and legally binding for the doctors, and verbal and visual support should be provided in addition to ICFs during patient informing. Presenting proof-based information at a clear, understandable, and appropriate reading level in consent texts would contribute the improvement of communication between urologists and patients in the preoperative and postoperative process, and would cause a better informing of the patients, especially on post-surgery results. We think that the cooperation of the concerned institutions is required for the revision of the ICFs available and the improvement of the texts according to the strategies recommended.

Ethics Committee Approval: Authors declared that the research was conducted according to the principles of the World Medical Association declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects” (amended in October 2013).

Informed Consent: Not required in this study.

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