

**ORIGINAL RESEARCH**

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**Assessment of readability level of informed consent forms used in intensive care units****Munise Yildiz, Betul Kozanhan, Mahmut Sami Tutar***University of Health Sciences, Konya Education and Research Hospital, Clinic of Anesthesiology and Reanimation, Konya, Turkey*Received 08 October 2018; Accepted 23 October 2018  
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**Abstract**

Informed consent forms are printed forms prepared to assist patients in the treatment process by explaining the indications, benefits and possible risks of medical practices. Readability describes understanding difficulty and is calculated by mathematical formulas. The study aimed to assess the readability level of “Informed Consent Forms” used in intensive care units. The informed consent forms from 45 hospitals in our country have been gathered. In each average form number of words, the average number of syllables and the average number of words with 4 or more syllables were manually calculated using the “Microsoft Office Excel 2016®” program. Their readability levels have been assessed with Atesman and Bezirci-Yilmaz readability formulas. The readability level of forms was “difficult” according to the Atesman readability formula and at “undergraduate level” according to the Bezirci-Yilmaz readability formula. The readability level of forms used in private hospitals was found to be significantly lower than that used in state and university hospitals ( $p=0.019$ ,  $p=0.012$ ). The average number of words and the average number of words with 4 or more syllables in forms were found to be significantly higher in private hospitals compared to state and university hospitals ( $p=0.004$ ,  $p=0.01$ ). It has been determined that the readability level of informed consent forms was at academic literacy level. To protect patient rights and to regulate patient-physician relationships by taking into account individuals rights, informed consent forms should be reviewed and that their readability levels should be adjusted to cover the overall educational level of individuals in the general population.

**Keywords:** Intensive care, informed consent form, readability**Introduction**

Informed consent forms are printed forms containing the diagnosis of disease, the proposed treatment method and the risks of this method for the patient’s health, the use and possible side effects of medical treatments and the outcomes of disease if the proposed treatment is refused [1]. The informational obligation is a debt for the physician and a right for the patient regarding the physician-patient relationship. Although the patient’s right to be informed is mentioned in the “Patients Rights Regulation” which has been put into force in Turkey in 1998, it is specified that the mentioned information should be clear and understandable enough and then must answer all possible questions. Before obtaining a patient’s informed consent for any medical intervention, the patient should be informed about the type, prognosis and possible side effects of the medical intervention, the outcomes of disease in case of

treatment refusal [2]. However, the reliability and update of, as well as their “readability” and “understandability,” are somewhat important because the value of information is limited by the ability of individuals to comprehend.

Although readability has been popular in recent years, it was based on past studies. It is a concept that provides some numerical data about texts and gives information about whether the text is easy to be understood by the reader at a certain level using characteristic features of syllables, words, and sentences of the language. Although this concept has been used mostly in inter-institutional correspondence, military organizations and healthcare companies in the past, today, it has become a concept which is used by linguistic scientists as well as other scientists and on which studies are performed frequently [3]. Besides the average number of words, the average number of syllables and the average number of words with 4 or more syllables, various criteria such as number synonym words must be placed in mathematical formulas to determine the readability level of a written text. To perform readability analysis, different formulas have been developed in Turkish as well as many foreign languages such as English and Spanish

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[4-7]. The Atesman and Bezirci-Yilmaz readability formulas, which have been described for determining the readability level of Turkish texts [5,6] and the Gunning-Fog and Flesch-Kincaid readability formulas, which measure the overall readability, [7,8] are commonly used readability formulas.

There is a limited number of studies on informed consent forms used in intensive care units in our country. The study aimed to assess the readability level of “Informed Consent Forms” that are mandatory to be obtained regarding both legal and ethical issues before any medical intervention performed in intensive care units.

## Materials and Methods

The study has been approved by the Education Planning Board of University of Health Sciences Konya Training and Research Hospital (Decision No: 1 March 2018/13-17). There are informed consent forms that are created according to certain standards and are routinely used in intensive care units of hospitals in our country. For the study, informed consent forms that were regularly used in intensive care units of 45 hospitals including university hospitals and training and research hospitals (n=15), state hospitals (n=15), and private hospitals (n=15) have been gathered. Each informed consent form was transferred to the “Microsoft Word 2016®” in the electronic environment. The institutional knowledge sections have been deleted to keep objectiveness of readability results. The average number of words, the average number of syllables and the average number of words with 4 or more syllables in these forms have been manually calculated using the “Microsoft Office Excel 2016®” program. For the calculation of the readability levels of each informed consent form, using Atesman and Bezirci-Yilmaz formulas data have been transferred to a computer software program [5,6]. The rate of medical terms within these 100 words has been determined as a percentage (%).

### Atesman Readability Formula:

It has been adapted into Turkish from Flesch’s Reading Ease Formula by Atesman (1997). It is a formula based on word and sentence length [5]. The Atesman readability formula gives a score on a scale ranging from 0–100; a higher score indicates that the text is easier to read while a lower number suggests that the text is more difficult to understand (Table 1).

### Atesman readability formula:

Readability Score =  $198.825 - 40.175 \times (\text{total number of syllables} / \text{total number of words}) - 2.610 \times (\text{total number of words} / \text{total number of sentences})$

### Bezirci-Yilmaz Readability Formula:

This formula was developed in 2010 based on the length of sentences in a text, the number of syllables in a word, and the statistical properties of Turkish language [6]. When the readability level is calculated, the number of syllables in each word is multiplied by its number. The readability level is formulated as follows:

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

ANW: average number of words

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

According to this formula, the readability level becomes more difficult as the length of sentences increases in texts. Moreover, an increase in the number of syllables in words makes it difficult to read words and indirectly sentences. This formula explains which class level a text represents according to the education system in our country: 1-8= primary school; 9-12= secondary school (high school); 12-16 = undergraduate level, and >16 = higher education. Statistical Analysis:

The SPSS® 21 (IBM Inc, USA) software was used to analyze the data. Categorical data were expressed as frequency and percentage. Numerical data were expressed as a mean  $\pm$  standard deviation. The One Way ANOVA and Kruskal-Wallis tests were used to compare numerical data between independent groups. All statistical analyzes have been performed bidirectionally at the 5% significance level and the 95% confidence interval.

## Results

Informed consent forms which were used in intensive care units of 45 medical institutions in our country have been included in the study. The mean readability value of these forms according to the Atesman and Bezirci-Yilmaz readability formulas as well as the average number of words, the average number of syllables and the average number of words with 4 or more syllables in these forms are shown Table 2. The mean readability value of these forms according to the Atesman readability formula was calculated as 41.8 for university hospitals and training and research hospitals, 43.0 for state hospitals and 35.7 for private hospitals, respectively. The readability level of informed consent forms was “difficult” according to the Atesman readability formula. The readability level of informed consent forms used in private hospitals was found to be significantly lower than those of informed consent forms used in state and university hospitals ( $p=0.019$ ). The mean readability value of these forms according to the Bezirci-Yilmaz readability formula was calculated as 14.9 for university hospitals and training and research hospitals, 14.4 for state hospitals and 17.7 for private hospitals, respectively. The readability level of informed consent forms was at “undergraduate level” according to the Bezirci-Yilmaz readability formula. According to the Bezirci-Yilmaz readability formula, there was a significant difference between the mean readability values of informed consent forms used in intensive care units of university hospitals and training and research hospitals, state hospitals and private hospitals ( $p=0.012$ ). The average number of words and the average number of words with 4 or more syllables in informed consent forms were found to be significantly higher in private hospitals compared to state and university hospitals ( $p=0.004$ ,  $p=0.01$ ). There was no significant difference between these institutions regarding the average number of syllables ( $p=0.361$ ). There was no significant difference between these institutions regarding the rate of medical terms in the 100-word text.

**Table 1.** Atesman Turkish Readability Formula

| Level     | Readability range |
|-----------|-------------------|
| Very easy | 90-100            |
| Easy      | 70-89             |
| Moderate  | 50-69             |
| Difficult | 30-49             |

**Table 2.** Readability Values of Informed Consent Forms

|                                                   | Private Hospital (n=15)<br>Mean $\pm$ SD | State Hospital (n=15)<br>Mean $\pm$ SD | University, Training and Research Hospital<br>(n=15) Mean $\pm$ SD | p     |
|---------------------------------------------------|------------------------------------------|----------------------------------------|--------------------------------------------------------------------|-------|
| Atesman readability formula*                      | 35.79 $\pm$ 6.23                         | 43.06 $\pm$ 9.10                       | 41.84 $\pm$ 5.21                                                   | 0.016 |
| Bezirci-Yilmaz readability formula**              | 17.70 $\pm$ 2.92                         | 14.40 $\pm$ 3.77                       | 14.99 $\pm$ 2.25                                                   | 0.012 |
| Average number of words **                        | 16.36 $\pm$ 2.44                         | 13.52 $\pm$ 3.24                       | 13.76 $\pm$ 1.91                                                   | 0.004 |
| Average number of syllables*                      | 2.99 $\pm$ 0.03                          | 2.99 $\pm$ 0.47                        | 3.01 $\pm$ 0.04                                                    | 0.361 |
| Average number of words with 4 or more syllables* | 5.59 $\pm$ 0.77                          | 4.59 $\pm$ 1.17                        | 4.79 $\pm$ 0.65                                                    | 0.010 |

\*One Way Anova

\*\*Kruskal-Wallis test

## Discussion

This study is the first study to analyze the readability level of written informed consent forms routinely used in intensive care units in our country. According to Atesman classification, it was found that the readability level of informed consent forms prepared for intensive care units was “difficult.” According to Bezirci classification, the readability level of written informed consent forms routinely used in intensive care units in our country, it was found “undergraduate level.”

Intensive care units are one of the hospital departments where many emergency interventions are performed in the presence of life-threatening and critical illnesses, where physicians and other healthcare professionals often have to make urgent decisions. It is complicated to get consent before medical interventions due to the nature of the job and generally there is not enough time.

However, as in other hospital departments in intensive care units, it is necessary to inform the patient about the possible complications that can occur during medical practice and request approval for this procedure. Ethically, the patient’s understanding of the proposed medical treatment is essential for the patient to make a conscious decision. In Patient Rights Regulation, it is stated that the patient himself/herself is the direct interlocutor of being informed and exceptional cases are addressed for children, saying that “if the patient is small and has a limited or absent power of judgment, his/her parent or guardian may request” [1]. It is clearly stated that if the patient does not have the capacity to make a decision about the medical intervention to be performed due to a disease or a similar reason, this intervention can be performed with consent obtained from his/her representative or the competent authority, person, or institution determined by a law [9]. Since most of the patients in intensive care units are unconscious and do not have the capacity to make a decision, it is not possible to get informed consent directly from the patient himself/herself. Therefore, indirect approval is mentioned if the patient is unable to give permission.

Informed consent, permission granted in full knowledge of the possible consequences, typically given by a doctor for treatment with knowledge of the potential risks and benefits. However, insufficiently understanding of this informed consent and thereby the medical intervention may lead to significant legal and ethical consequences. Although this is the first study that analyzed the readability level of written informed consent forms routinely used in intensive care units in our country, the readability level of informed consent forms used in various hospital departments

had been previously reported. Hancı et al. analyzed the readability level of anesthesia informed consent forms and reported that the readability levels of anesthesia consent forms used in university hospitals were “very low” according to the Atesman readability formula [4]. They also showed that the readability level of anesthesia consent forms used in training and research hospitals and state hospital were “low” according to the Atesman readability formula [4]. In another study evaluating informed consent forms which are routinely used for open, endoscopic, and laparoscopic urological surgery, it was reported that the readability level of all consent forms was “moderately difficult” according to the Atesman readability formula [10]. The same forms were at “high school level” according to the Bezirci-Yilmaz readability formula [10]. In a study assessing the readability index of informed consent forms used for contrast materials, it was found to be at “educational level above undergraduate” according to the SMOG readability formula [11]. Similar to these studies, we found that the readability level of informed consent forms prepared for intensive care units was “difficult” according to the Atesman readability formula and at “undergraduate level” according to the Bezirci-Yilmaz readability formula.

Today, many different formulas have been described to calculate readability level. However, each language has its unique word and sentence structures. Since Turkish is an agglutinative language, the number of letters and syllables in words can be high. Therefore, a meaning which is described with a word in Turkish can sometimes be explained with a sentence in another language [12]. Hence, the use of formulas which are used for texts in a foreign language but are not defined for our language may lead to unhealthy and improper outcomes [13]. For these reasons, instead of formulas such as FLESCHE and SMOG, which are frequently used in readability analyzes in the literature, the readability formulas developed for the Turkish language were preferred in our study.

Determination of the educational level by analyzing the readability level of a written text may give an idea about the understandability of that text. Klare has described readability as that all linguistic features in the text are more or less acceptable to the reader and has specified that readability is a factor that affects the performance of the reader [14]. According to Atesman, there are some differences between readability and understandability. While the content of the text is significant in understandability readability based on the fact that the written text is easy or difficult to read for individuals [6]. According to the results of this study, we found that the readability level of informed consent forms used in intensive care units in our country was “difficult.” However, we did not assess

the understandability level of these forms by healthcare recipients. In a study, that was conducted to determine the attitudes of patients in informed consent practices and to identify the problems experienced in this process in 2014, it has been found that only 34% of the participants read the entire consent form and, 55.7% of participants have not understood the forms. [15]. It can be assumed that the level of understandability of informed consent forms may be low when it is taken into account that the levels of readability according to our findings require training at “undergraduate level” according to the education system in our country.

If individuals receiving health care have a lower educational level than the readability level of informed consent forms, a “readability gap” can be mentioned. This means that patients or their legal representatives cannot fully understand medical procedures [16]. Studies have found that there is a relationship between the overall educational level and comprehension level. “Health literacy” is defined as the ability to obtain, read, understand, and use healthcare information to make appropriate health decisions and follow instructions for treatment. It has been found that the average duration of education in the US is 12.6 years and that approximately 40% of the population have inadequate health literacy. For this reason, written health materials recommended to be arranged according to the sixth grade level of education or below to maximize the understandability level of the content of medical consent forms [17].

According to the data from the Turkish Statistical Institute (TUIK, 2016), 5% of individuals aged 25 years and over in Turkey are illiterate, but 16% were university graduates [18]. In a study conducted in 2014, it was determined that the general health literacy index of Turkey was 30.4 and that 64.6% of the adult population of Turkey was in insufficient health literacy categories [19]. Problematic health literacy leads to the fact that individuals have less information about their illnesses and treatments, are more exposed to medical malpractice and have difficulties in reaching healthcare services. Informed consent forms should be reviewed to protect patient rights and to regulate patient-physician relationships by taking into account patient rights. Their readability levels should be adjusted to cover the overall educational level of individuals in the general population (six years of education or below). Patients with the lowest educational level are included in this way.

Several suggestions for an adequate understanding of the informed consent forms by the readers are; limiting medical words, choosing words with three or fewer syllables if possible, using short and simple sentences and dividing the paragraphs if necessary.

In this study, informed consent forms which were routinely used in intensive care units of 45 hospitals (including university hospitals and training and research hospitals, state hospitals, and private hospitals) in Turkey were assessed. Therefore, the results of our study are difficult to reflect the general status of our country directly. It will be more appropriate to give information about the general situation in our country with further extensive studies.

## Conclusion

This study is the first study to analyze the readability level of written informed consent forms routinely used in intensive care

units in our country. According to Atesman classification, it was found that the readability level of informed consent forms prepared for intensive care units was “difficult.” According to Bezirci classification, the readability level of written informed consent forms routinely used in intensive care units in our country, it was found “undergraduate level.”

As a result, it has been found that the readability level of informed consent forms used in intensive care units is “difficult,” which is an important step in the protection of patient rights and the prevention of legal problems in the practice of health. The readability level of “Informed Consent Forms” that are mandatory to be obtained regarding both legal and ethical issues before medical interventions should be restructured with the cooperation of active associations and institutions in accordance with the proposed strategies.

## Competing interests

*The authors declare that they have no competing interest*

## Financial Disclosure

*The financial support for this study was provided by the investigators themselves.*

## Ethical approval

*The study was approved by the Education Planning Board of University of Health Sciences Konya Training and Research Hospital (Decision No: 1 March 2018/13-17).*

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