Original Article

Internal Medicine

DAHUDER Medical Journal
e-ISSN: 2791-9250

Comprehensibility Levels of Informed Consent Forms in a State Hospital Internal Medicine Clinic: A Descriptive Study

Gokhan Tazegül

Department of Internal Medicine, Polatlı Duatepe State Hospital, Ankara, Turkey

ABSTRACT

Objectives: Herein, we aimed to determine the comprehensibility levels of written informed consent forms in a state hospital internal medicine clinic.

Methods: Twenty-eight informed consent forms fordiagnostic interventions, treatment applications, and hospitalization processes in a state hospital internal medicine clinic were evaluated with the comprehensibility indexes developed by Ateşman and Bezirci-Yılmaz. We evaluated comprehensibility in four main groups: primary (1st-8th grade), high school (9th-12th grade), undergraduate (13th-16th grade), and graduate education (over 16th grade).

Results: According to both comprehensibility indexes, all forms required at least a high school education. According to Ateşman, median comprehensibility was at the 13th-14th grade; according to Bezirci-Yılmaz, a median of 14.6 years of education was required for comprehensibility.

Conclusion: For comprehensibility of the informed consent forms used in the internal medicine clinic, at least high school and median university-level education were required. Considering the rate of population with a high school or higher education degree in Turkey was 43% in 2020, it is predicted that the patients' comprehensibility of the written informed consent would be seriously low. Immediate regulations are required ethically and legally to increase the comprehensibility of existing written informed consent forms throughout society.

Keywords: comprehensibility, consent forms, informed consent, internal medicine

In daily clinical practice, informing patients before procedures and ensuring that patients participate in the process is a patient's right, an ethical rule, and a legal obligation.[1] This information is provided verbally and in writing within the "informed consent" between the physician and the patient.Informed consent is formed by explaining in a detailed, understandable, and structured way why the intervention is needed, how the intervention will be done, the benefits that the person will receive from this intervention, and the possible harm that may occur due to the procedure, the process they will experience if they are not treated, and the alternative options in the treatment.The informed consent process is concluded by the patient's verbal and written notification of the decision (either approval or refusal) about the procedure, where the patient has read and understood the information presented in writing.[2]

In addition to fulfilling ethical and legal requirements, the patient must understand the written informed consent forms to protect physicians from medical malpractice. One of the definitions used to describe the readability of written texts is comprehensibility.The comprehensibility level can be measured

Received: *January 16, 2022****; Accepted:*** *January 21, 2022****; Published Online:*** *April 29, 2022*

How to cite this article: *Tazegül G., Comprehensibility Levels of Informed Consent Forms in a State Hospital Internal Medicine Clinic: A Descriptive Study. DAHUDER M J 2022, 2(2):36-41.*

Address for correspondence: *Gokhan Tazegül, M.D. Specialist, Department of Internal Medicine, Polatlı Duatepe State Hospital, Ankara, Turkey. E-mail: drgtazegul@gmail.com Phone: +90 531 661 65 18*

objectively using various mathematical formulas, and the measured values are defined by education level equivalencies (i.e., primary school, high school, undergraduate, or graduate level).[3] Various scoring systems use parameters such as the number of sentences in the text, the number of words in the sentences, and the number of syllables in words to calculate comprehensibility.[4-6] For Turkish texts, criteria developed by Ateşman and Bezirci and Yılmazevaluate comprehensibility.[7, 8]

According to their preference, each hospital or physician may have informed consent forms specific to the diagnostic procedures, treatment applications, or hospitalization processes that they use in daily clinical practice. In this study, we aimed to determine the comprehensibility levels of written informed consent forms used daily in a state hospital internal medicine clinic, define the comprehensibility of these texts, and determine which texts could be read according to education level.

METHODS

Herein, we evaluated twenty-eight different standardized informed consent forms developed by a state hospital for daily clinical use in the internal medicine clinic. Written permission was obtained from the state hospital administration to use informed consent forms.

Various methods have been developed to evaluate comprehensibility, using parameters such as the number of sentences in the text, how many words these sentences consist of, how many syllables each word has, and the rate of professional terminology use. The result obtained with these calculations expresses the text's comprehensibility according to the people's education level. Although there are more than forty formulas accepted as comprehensibility criteria , in this study, two separate comprehensibility criteria, developed by Ateşman in 1997 and Bezirci and Yılmaz in 2010 were used to evaluate Turkish informed consent texts.[2, 7, 8]

Ateşman Comprehensibility Index

Ateşman Comprehensibility Indexis a mathematical method to calculate comprehensibility that considers the length of words and sentences. According to Ateşman's formula, the average sentence length in Turkish is 9-10 words, and the average length of words is 2.6 syllables. The results obtained with the Ateşman Readability Criterion formula are determined as a readability value between 0-100; higher values indicate easier-to-read texts.[7] Ateşman Comprehensibility Indexwas applied as:198.825 - 40.175 x word length (total syllables / total words) - 2.610 x sentence length (total words/ total sentences). The numerical value obtained determined the text's comprehensibility according to the reader's education level (Table 1).

Bezirci-YılmazComprehensibility Index

The comprehensibility index developed by Bezirci and Yılmaz takes into account the number of words in sentences, the number of syllables in words, and the distribution of words according to the syllable counts (Table 2). The result obtained with the Bezirci-YılmazComprehensibility Indexreveals the comprehensibility level as the number of years the person has been educated. When this level is evaluated considering the current education system in Turkey, it provides a grouping of readability according to education levels (Table 3).[8]

Table 1. The relationship between the Ateşman comprehensibility index and the comprehensibility level

Index	Comprehensibility Level
90 - 100	Can be easily understood by students in 4th grade and below
80 – 89	Can be easily understood by students in 5 th and 6 th grade
70 – 79	Can be easily understood by students in 7 th and 8 th grade
60 – 69	Can be easily understood by students in 9 th and 10 th grade
50 – 59	Can be easily understood by students in 11 th and 12 th grade
40 – 49	Can be easily understood by undergraduates
30 – 39	Can be easily understood by university graduates
< 29	Can be easily understood by university postgraduates

Table 2. Bezirci-Yilmaz comprehensibility index formula

Bezirci-Yilmaz comprehensibility index = $\sqrt{MWC[(S3 \times 0.84) + (S4 \times 1.5) + (S5 \times 3.5) + (S6 \times 26.25)]}$

MWC: mean word count; S3: mean number of words with three syllables; S4: mean number of words with four syllables; S5: mean number of words with five syllables; S6: mean number of words with ≥ six syllables

Table 3. The relationship between the Bezirci-Yilmaz comprehensibility index and the comprehensibility level

Comprehensibility level (years)	Education level
1–8	Primary school
9–12	High school
13–16	Undergraduate
> 16	Postgraduate

Data acquisition and evaluation

Each of the twenty-eight informed consent forms was transferred to the Microsoft Word program. Before evaluating comprehensibility, the titles of the informed consent forms were removed to prevent any incorrect effect on the comprehensibility level. Then, the forms were evaluated in the context of the comprehensibility formulas developed for the Turkish language by Ateşman, and Bezirci-Yilmaz.[7, 8] When performing these procedures, the computer software developed by Bezirci-Yilmaz was used. The purpose of informed consent forms was categorized into three main groups: diagnostic interventions, treatment applications, and hospitalization processes. In addition, the ratio of medical terms to the total number of words was determined by counting the medical terms used in the informed consent forms, and this ratio was expressed as a percentage. The minimum level of education required for the comprehensibility of the informed consent forms was evaluated in 4 main groups: primary (1st-8th grade), high school (9th-12thgrade), undergraduate (13th-16th grade), and graduate education (over 16th grade).

Statistical analysis

Data were analyzed using SPSS for Windows version 23.0 (SPSS, Chicago, Illinois, USA). Continuous variables were expressed as median (minimum-maximum) and categorical data as numbers and percentages. Chi-square tests were used to compare categorical data and Mann-Whitney U test for continuous variables. $P < 0.05$ was accepted as the statistical significance limit for all statistical tests.

RESULTS

The study evaluated twenty-eight informed consent forms in routine clinical use in a state hospital internal medicine clinic. Of these informed consent forms, 7 (25%) were related to the diagnostic interventions, 15 (53.6%) informed consent forms were for treatment applications, and 6 (21.4%) were for hospitalization processes. Informed consent forms had a median length of 607 words (260-2349 words). The median number of medical terms in the informed consent texts included 13 words (3-77 words), and the median percentage of medical terms was 1.96% (0.006%-12.2%).

The comprehensibility levels of all informed consent forms were evaluated with Ateşman and Bezirci-Yılmaz's comprehensibility indexes. According to the Ateşman comprehensibility index, the median comprehensibility level was 44.8 points (22.9-58.1), which can be interpreted as comprehensible by 13th and 14th -grade students. When evaluated with the

Table 4. Comprehensibility levels of the consent forms according to the Ateşman and the Bezirci-Yılmaz comprehensibility indexes

	Ateşman	Bezirci-Yılmaz
Primary school (1st-8th years)	0 (0%)	0 (0%)
High school (9th-12th years)	10 (35.7%)	13 (46.5%)
Undergraduate (13th-16th years)	17 (60.7%)	9 (32.1%)
Postgraduate (> 16 years)	1 (3.6%)	6 (21.4%)

Bezirci-Yılmaz comprehensibility index, the median comprehensibility level was 14.6 years (8.6-19.2 years), which can be interpreted as comprehensible at the undergraduate level. The distribution of comprehensibility levels of informed consent forms according to both comprehensibility indexes is presented in Table 4. None of the informed consent forms were readable at a primary school education level. 35.7% of the informed consent forms according to the Ateşman comprehensibility index and 46.5% according to the Bezirci-Yılmaz comprehensibility index were readable at the high school education level.

Informed consent forms were also divided into two groups by dividing from the median value of each variable: word count, medical term count, and medical term percentage. However, no significant difference was observed between these groups regarding comprehensibility. When the consent forms were analyzed according to their intended use, the comprehensibility of the informed consent forms related to the diagnostic interventions had higher comprehensibility according to the Ateşman ($p = 0.006$, chi-square test), and to the Bezirci-Yılmaz comprehensibility indexes ($p = 0.038$, chi-square test) (Table 5).

DISCUSSION

It is of ethical and legal importance that the written informed consent forms are comprehensible. This study aimed to determine the comprehensibility levels of informed consent forms used in daily clinical practice in a state hospital internal medicine clinic objectively, with the comprehensibility indexes developed by Ateşman and Bezirci-Yılmaz, and to define the corresponding level of education required for these texts. We determined that at least high school students can read informed consent forms according to both comprehensibility indexes. We observed that none of the included informed consent forms were readable at a primary school education level, and 35.7% according to the Ateşman comprehensibility index and 46.5% according to the Bezirci-Yılmaz comprehensibility index were comprehensible at a high school education level. In both indexes, we observed that the comprehensibility of the consent forms related to the diagnostic procedures are easier to comprehend, while the consent forms related to the hospitalization procedures are more challenging to comprehend. According to the Turkish Statistical Institute National Education Statistics Database, the rate of population with a high school or higher education degree in Turkey was 24.5% in 2008, and this percentage increased every year and reached 43% in 2020. The proportion of the population with at least an associate university degree has increased from 9.1% to 21.6%.9 According to the United Nations Educational Scientific and Cultural Organization (UNESCO) 2017 data, the average education level of Turkey was 8.27 years.10 When the comprehensibility of the informed consent forms is evaluated in the light of these statistical data, we believe that the comprehensibility of the informed consent forms used in daily clinical practice is seriously low.

Table 5. A comparison of comprehensibility levels of the consent forms according to their purpose

		Diagnostic interventions (n = 7)	Treatment applications (n = 15)	Hospitalization processes (n = 6)
Ateşman	High school (9^{th} - 12^{th} years)	6 (85.7%)	4 (26.7%)	0 (0%)
	Undergraduate (13^{th} - 16^{th} years)	1 (14.3%)	11 (73.3%)	5 (83.3%)
	Postgraduate (> 16 years)	0 (0%)	0 (0%)	1 (16.7%)
Bezirci-Yılmaz	High school (9^{th} - 12^{th} years)	6 (85.7%)	7 (46.7%)	0 (0%)
	Undergraduate (13^{th} - 16th years)	0 (0%)	5 (33.3%)	4 (66.7%)
	Postgraduate (> 16 years)	1 (14.3%)	3 (20%)	2 (33.3%)

The average education level of adults in the USA was determined to be at the 8th-grade level, and the American Medical Association and the National Institutes of Health recommended that the informed consent forms used for invasive procedures in the USA should be comprehensible at an education level corresponding to 6th grade.[11]However, Eltorai *et al*. evaluated the comprehensibility of the informed consent forms using seven different formulas, mainly Flesch-Kincaid; and they determined that the informed consent forms used for invasive procedures had a readability level corresponding to an average of 15 years of education, similar to our study.[12]

Although there is no clear recommendation about the comprehensibility of informed consent forms in Turkey, there are studies on the comprehensibility of Turkish informed consent forms used for various purposes. Ebem *et al*. analyzed 90 separate intramuscular and intravenous informed consent and determined the average comprehensibility was at 11th and 12th-grade education levels.[13] Ay *et al*. evaluated the informed consent forms used before ophthalmological surgical procedures, and Boztaş *et al*.evaluated the informed consent forms used before anesthesia, which both reported similar comprehensibility levels.[14, 15] The median comprehensibility in our study was at a 13th and 14th-grade education level according to the Ateşman comprehensibility index, and when evaluated with the Bezirci-Yılmaz comprehensibility index, the median comprehensibility was at 14.6 years. Compared to similar studies in the literature, informed consent forms used in internal medicine clinics require a higher level of education, and urgent correction and improvement are required to increase comprehensibility.

The percentage of medical terms in the informed consent forms is another factor that can affect the comprehensibility of the text. Ebem *et al*. reported that the use of medical term percentage in intramuscular and intravenous informed consent forms was 2.6%.[13] Ay *et al*.reporteda 3.7% medical term percentage in informed consent forms used for ophthalmological surgical procedures, and Boztaş *et al*. reported the average percentage of medical terms as 4% in pre-anesthesia consent forms.[14, 15] Although the median ratio of medical term percentage in our study was 1.96%, which is lower than the ratios reported in the literature, this difference may have arisen due to the differences in the procedures defined in the informed consent texts.

There are several limitations to our study. We considered the sentence length, word count, and the number of syllables in words. However, before a possible diagnostic procedure or treatment application, a patient's anxiety level may be higher than normal, which can affect the comprehensibility of the informed consent form. In addition, the font choice and the font size of the informed consent texts included in this study were not taken into account, which also may affect the comprehensibility of the text. Further studies of the comprehensibility levels of informed consent forms, focusing on new models, including characteristics such as education level, age, mental state, and patients' visual acuity, are necessary.

Our study demonstrated that the written informed consent forms used in daily clinical practice in a state hospital internal medicine clinic required at least a high school education level to be comprehensible. The median comprehensibility was at university-level education. Considering the statistics of the population with a high school or higher education level in Turkey, it is predicted that the patients' comprehensibility of the written informed consent forms is seriously low. Although further studies are required that consider other factors of comprehensibility of a text on this subject; urgent regulations are needed, ethically and legally, to increase the comprehensibility of existing written informed consent forms throughout society.

CONCLUSION

Ethical considerations:Ethics committee approval is not required as the author did not use human or experimental animal data in this study. The permission to use consent forms was obtained from the hospital administration and presented with the manuscript.

Conflicts of interest: The author declares none

Author Contributions: Study Conception: GT; Study Design: GT; Supervision: GT; Funding: GT; Materials: GT; Data Collection and/or Processing: GT; Statistical Analysis and/or Data Interpretation: GT; Literature Review: GT; Writer: GT; Critical Review: GT.

Financial disclosure

The author declares none.

Acknowledgments

The author declares none.

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