

ORIGINAL ARTICLE

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Evaluation of the readability of informed consent forms commonly used in dermatology and cosmetology in Türkiye

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Abstract

Informed consent forms (ICFs) must contain all the necessary information related to medical interventions and be comprehensible to the patient. This study aims to determine the readability levels of the ICFs listed on the official website of the Turkish Dermatology Association. A total of 23 consent forms, accessible on the website (<https://turkdermatoloji.org.tr/icerik/detay/289>) of the Turkish Dermatology Association, were incorporated into the study and classified into seven distinct categories. Twenty-three consent forms available on the Turkish Dermatology Association's website were included in the study and categorized into seven groups. The texts of these forms were loaded into readability software. To ascertain the readability levels of the included texts, the mean number of words per sentence, the mean word count, the mean number of words with four syllables or more, and the mean number of syllables were calculated using the Bezirci-Yılmaz and Ateşman formulas. These data were then statistically compared. The mean readability of all ICFs was at the high school level according to the Bezirci-Yılmaz formula and at a medium difficulty level according to the Ateşman formula. According to the Bezirci-Yılmaz formula, the Methotrexate ICF was at an academic level, while the ICFs for Cosmetic Procedures with Energy-Based Devices and Superficial Skin Renewal Methods were at the undergraduate level. When comparing the readability values of Bezirci-Yılmaz and Ateşman, a significant difference was found between five groups with multiple consent forms ($p=0.006$ for both). Pairwise comparisons revealed that the low readability of the ICFs for Cosmetic Procedures with Energy-Based Devices was responsible for this significant difference. The readability of these forms was at the undergraduate level, according to Bezirci-Yılmaz, and at a challenging level, according to Ateşman. The readability levels of the ICFs available on the official website of the Turkish Dermatology Association are low. These consent forms should be revised to guarantee that patients are sufficiently informed about the medical procedures they will undergo. Otherwise, patients and physicians may face legal challenges due to potential complications.

Keywords: Dermatology, cosmetics, consent forms, health literacy, readability, malpractice

Introduction

For a medical intervention to be legally valid, it must be performed by authorized individuals for the correct indication, by the rules and standards of medical science, and with the individual's informed consent [1]. Even if a physician performs a medical procedure by the laws and standards, they may still be held legally responsible for complications if informed consent is not obtained [2]. Informed consent is the legal responsibility of physicians and other healthcare providers. Informed consent involves explaining a medical intervention's risks, benefits, and alternatives to the patient and obtaining their approval for the

procedure. Physicians must obtain informed consent from their patients to protect them and themselves from legal issues in case of complications [3].

In preparing informed consent forms (ICFs) for medical interventions, it is essential to consider the potential impact of language barriers, the population's educational levels, and health literacy [4].

The term 'health literacy' describes an individual's capacity to comprehend, interpret, and act upon medical information when it is presented to them [5]. In Türkiye, the overall health literacy index is 30.4, 40.1% demonstrating limited health

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literacy and with 24% of the population exhibiting inadequate health literacy [6].

When obtaining informed consent, attention should be paid to linguistic and cultural differences. According to the relevant legislation, the patient's native language must be used to obtain their consent [7].

Physicians should evaluate their patients' decision-making abilities and, if inadequate, obtain information and consent from the patient's primary caregiver. In cases of uncertainty, psychiatric or neurological consultations should be sought to assess decision-making capacity [4].

ICFs should be written in a simple language that individuals with the lowest level of education can understand. The American Medical Association recommends developing patient-targeted written materials at a sixth-grade reading level or below [8].

Reading comprehension depends on both literacy level and the characteristics of the text. Factors such as word familiarity, word length, number of syllables, number of words in a sentence, sentence length, syntax, and the presentation of the text all affect readability. Readability describes how easily a text can be read and understood [9,10]. The concept of readability has long been employed to assess the suitability of a written text in a specific language for the reader's level of comprehension [11].

To ensure that physicians who perform medical interventions according to the indication and the rules of medical science do not face legal issues due to complications, ICFs must contain all the necessary information related to the medical intervention and be understandable to the patient. The objective of this study is to evaluate the readability levels of ICFs of dermatology and cosmetology, which are accessible on the official website of the Turkish Dermatology Association, by employing the Bezirci-Yılmaz and Ateşman readability formulas, which have been specifically designed for use with the Turkish language [9,10,12].

Material and Methods

This study received approval (No. 01.07.2024/12) from the Clinical Research Ethics Committee of Kahramanmaraş Sütçü İmam University. This research is descriptive. For the study data, 23 consent forms related to commonly performed procedures in dermatology and cosmetology available on the Turkish Dermatology Association's website (<https://turkdermatoloji.org.tr/icerik/detay/289>) were utilized. The texts of the included consent forms were transferred into a text document (.txt format) and uploaded into readability software. The texts were then imported into the software program. The Bezirci-Yılmaz and Ateşman formulas were used to calculate the mean number of words per sentence, the mean word count, the mean number of words with four or more syllables, and the mean number of syllables to assess the readability levels.

Ateşman Readability Index

The Ateşman Readability Index was developed in 1997 by Ateşman and is based on the Flesch Reading Ease Formula, adapted to Turkish. The Ateşman formula is used to evaluate the readability of a text, taking into account the length of words and sentences. According to this formula, a text is classified as very easy to read if it scores between 90 and 100, as easy between 70 and 89, as moderate between 50 and 69, as difficult between 30 and 49, and as very difficult to read if it scores between 1 and 29 [9].

The Ateşman readability score is calculated as follows:

Readability Score = $198.825 - 40.175 \times (\text{total syllables}/\text{total words}) - 2.610 \times (\text{total words}/\text{total sentences})^9$

Bezirci-Yılmaz Readability Formula

Bezirci and Yılmaz adapted various readability measures developed for English and proposed a new readability criterion for Turkish, taking into account the statistical properties of the Turkish language. The formula considers the different academic levels (1-8 elementary, 9-12 high school, 12-16 undergraduate, 16 and above academic education) [10].

NRS: $\sqrt{\text{AWC} \times [(\text{H3} \times 0.84) + (\text{H4} \times 1.5) + (\text{H5} \times 3.5) + (\text{H6} \times 26.25)]}$

NRS: New readability score

AWC: Mean word count

H3: Mean count of three-syllable words

H4: Mean count of four-syllable words

H5: Mean count of five-syllable words

H6: Mean count of six-syllable words

Statistical Analysis

Data analysis was conducted using SPSS® version 15 (IBM Inc., USA). The descriptive statistics in the study are reported as mean±standard deviation (SD), minimum and maximum values for continuous variables, and frequencies (n) with percentages for categorical data. For continuous variables that did not exhibit a normal distribution, the Mann-Whitney U test was applied to compare two independent groups. In contrast, the Kruskal-Wallis test was used for comparisons involving three or more independent groups. When significant differences were detected with the Kruskal-Wallis test, the Bonferroni-corrected Mann-Whitney U test was performed for pairwise comparisons. A p-value of less than 0.05 was considered statistically significant.

Results

The study included 23 ICFs from 7 subgroups of standard procedures in dermatology and cosmetology, obtained from the Turkish Dermatology Association's website (<https://turkdermatoloji.org.tr/icerik/detay/289>) [12].

The mean Ateşman readability score of the ICFs was 52.01 ± 7.11 , and the mean Bezirci-Yılmaz readability score was 11.15 ± 2.42 . Accordingly, the overall readability of the ICFs was at the high school level and of moderate difficulty. The mean number of sentences across all forms was 62.96 ± 25.21 , the mean word count was 591.22 ± 151.46 , and the mean number of words with four or more syllables was 195.61 ± 54.03 . The mean number of words per sentence was 10.00 ± 2.49 , and the mean number of syllables per word was 2.93 ± 0.35 . Other values are presented in Table 1.

When analyzed by group, the readability of the ICFs for Cosmetic Procedures with Energy-Based Devices and Drug Applications was difficult according to the Ateşman formula. At the same time, other consent forms were moderately difficult. According to the Bezirci-Yılmaz formula, Drug Applications were at an academic level; the ICFs for Cosmetic Procedures with Energy-Based Devices and Superficial Skin Renewal Methods were at the undergraduate level; and ICFs for Needle-Injection Cosmetic Procedures, Phototherapy Applications, and Allergy Testing were at the high school level. Only the Minor Surgical Procedures were at the elementary level (Table 2).

When analyzed individually, the readability scores of the seven groups were as follows: Cosmetic Procedures with Energy-Based Devices: Ateşman 47.76 ± 4.25 , Bezirci-Yılmaz 12.56 ± 1.68 Needle-Injection Cosmetic Procedures: Ateşman 51.56 ± 2.95 , Bezirci-Yılmaz 11.65 ± 0.74 Superficial Skin Renewal Methods: Ateşman 50.26 ± 0.51 , Bezirci-Yılmaz 12.91 ± 0.16 Phototherapy Applications: Ateşman 58.69 ± 1.91 , Bezirci-Yılmaz 8.45 ± 0.97 Allergy Testing Applications: Ateşman 59.16 ± 2.32 , Bezirci-Yılmaz 8.88 ± 0.58 . Other values are presented in Table 2 and Figure 1.

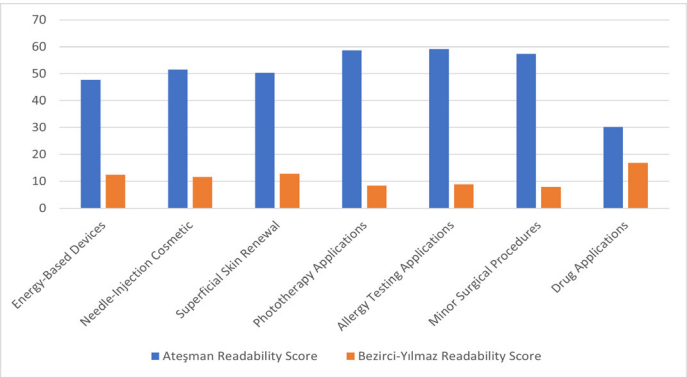


Figure 1. Readability scores of consent forms in dermatology and cosmetology

A significant difference was found between the Bezirci-Yılmaz and Ateşman readability scores for the five groups that contained more than one ICF ($p=0.006$ for both). Pairwise comparisons revealed that the low readability of the ICFs for Cosmetic Procedures with Energy-Based Devices was responsible for this significant difference. According to the Bezirci-Yılmaz formula, these ICFs were at the undergraduate level, whereas the Ateşman formula classified them as difficult (Table 2).

Among the seven groups, significant differences were found in the mean number of sentences, words, syllables per text, words with four or more syllables, character count, and letter count per text. However, there was no significant difference in the mean number of syllables per word (Table 2).

When each ICF was analyzed individually, the best readability score according to the Ateşman formula was for the “Skin Prick Test,” while the worst was for the “Methotrexate” ICF. According to the Bezirci-Yılmaz formula, the best readability score was for the “Local PUVA Phototherapy,” while the worst was for the “Methotrexate” ICF (Table 3).

Table 1. The mean readability scores for all consent forms within the fields of dermatology and cosmetology

	Scores mean±SD	Median (min-max)
Ateşman readability	52.01±7.11 (moderate difficulty)	52.5 (30.1-61.1)
Bezirci-Yılmaz readability	11.15±2.42 (high school level)	11.4 (7.3-17.0)
Number of sentences	62.96±25.21	57 (27-158)
Word count	591.22±151.46	547 (425-1069)
Number of words with four or more syllables (polysyllabic)	195.61±54.03	202 (118-354)
Syllable count	1732.22±502.82	1661 (775-3292)
Character count	5102.30±1323.67	4611 (3787-9780)
Letter count	4098.48±1053.92	3888 (2905-7529)
Word count per sentence	10.00±2.49	10.6 (5.9-16.1)
Syllable count per word	2.93±0.35	3.0 (1.33-3.15)

SD: standard deviation, Min: minimum, Max: maximum

Table 2. Mean readability scores and text content of consent forms in dermatology and cosmetology

	Cosmetic procedures with energy-based devices						
	Cosmetic procedures with energy-based devices	Needle-injection cosmetic procedures	Superficial skin renewal methods	Phototherapy applications	Allergy testing applications	Minor surgical procedures	Drug applications
Number of consents	6	6	2	4	3	1	1
Ateşman readability score	47.76±4.25	51.56±2.95	50.26±0.51	58.69±1.91	59.16±2.32	57.45	30.16
Bezirci-Yilmaz readability score	12.56±1.68	11.65±0.74	12.91±0.16	8.45±0.97	8.88±0.58	7.94	17.01
Number of sentences	50±5.55	58.17±10.02	71.5±10.61	76.50±14.97	55.0±1.73	158	27
Word count	567.17±38.87	619.67±75.26	811.5±64.34	512.5±48.11	433.0±8.54	1069	436
Number of words with four or more syllables	201±13.5	211.33±21.20	261±24.04	162.75±12.73	122.33±7.51	354	131
Syllable count	1710.5±114.58	1836.67±205.06	2400.5±241.12	1310.25±358.61	1283.67±40.27	3292	1373
Character count	4800.83±340.81	5152.67±667.40	6782.5±630.03	4656±512.98	3958.67±83.29	9780	3787
Letter count	3964.5±263.89	4273.83±482.19	5549.5±587.61	3527.25±329.82	2960.67±86.23	7529	3216
Mean word count per sentence	11.44±1.32	10.73±0.72	11.41±0.79	6.82±1.05	7.88±0.37	6.77	16.15
Mean syllable count per word	3.01±0.05	2.96±0.07	2.96±0.06	2.61±0.85	2.96±0.05	3.08	3.15

Table 3. Readability scores and text content of consent forms in dermatology and cosmetology

	Ateşman	Bet	Number of sentences	Word count	Number of words with four or more syllables	Syllable count	Character count	Letter count	Mean word count per sentence	Mean syllable count per word
Cosmetic procedures with light-based devices										
Ablative laser skin resurfacing	41.72	14.94	45	597	214	1820	5206	4202	13.27	3.05
Non-ablative laser skin resurfacing	44.22	13.41	44	546	208	1661	4562	3872	12.41	3.04
Q-switched laser tattoo removal	46.77	13.50	52	603	211	1828	5185	4220	11.60	3.03
Vascular laser treatment	52.59	11.28	54	601	193	1753	4856	4085	11.13	2.92
Laser hair removal	50.19	11.88	47	509	178	1525	4385	3520	10.83	3.00
Radiofrequency	51.11	10.37	58	547	202	1676	4611	3888	9.43	3.06
Overall difficulty level	Difficult (Ateşman)	Undergraduate (Bezirci-Yılmaz)								
Needle-injection cosmetic procedures										
Botulinum toxin application	52.29	11.83	58	642	224	1880	5266	4347	11.07	2.93
Filler application	53.57	11.50	57	628	214	1821	5091	4207	11.02	2.90
Injection lipolysis	53.19	11.42	67	702	228	2067	6102	4842	10.48	2.94

Table 3. Readability scores and text content of consent forms in dermatology and cosmetology

	Ateşman	Bet	Number of sentences	Word count	Number of words with four or more syllables	Syllable count	Character count	Letter count	Mean word count per sentence	Mean syllable count per word
Sclerotherapy	54.16	10.38	72	687	227	2048	5625	4775	9.54	2.98
Mesotherapy	46.43	12.39	49	520	202	1614	4396	3725	10.61	3.10
PRP (Platelet-Rich Plasma) therapy	49.73	12.38	46	539	173	1590	4436	3747	11.72	2.95
Overall difficulty level	Moderate (Ateşman)	High School (Bezirci-Yılmaz)								
Superficial skin renewal methods										
Dermaroller (Microneedling)	50.63	13.02	64	766	244	2230	6337	5134	11.97	2.91
Chemical peeling	49.90	12.79	79	857	278	2571	7228	5965	10.85	3.00
Overall difficulty level	Moderate (Ateşman)	Bachelor's degree								
Phototherapy applications										
Narrowband UVB phototherapy	59.28	8.42	74	480	154	1465	4398	3316	6.49	3.05
Broadband UVB phototherapy	59.09	8.26	74	478	154	1462	4378	3308	6.46	3.06
Local PUA phototherapy	60.45	7.38	97	581	181	775	5425	4008	5.99	1.33
Systemic PUVA phototherapy	55.96	9.75	61	511	162	1539	4423	3477	8.38	3.01
Overall difficulty level	Moderate (Ateşman)	High School								
Allergy testing applications										
Photo patch (Patch) test	56.57	9.55	54	442	131	1330	4054	3060	8.19	3.01
Atopy patch test	59.88	8.52	57	425	118	1264	3922	2905	7.46	2.97
Skin prick test (SPT)	61.05	8.57	54	432	118	1257	3900	2917	8.00	2.91
Overall difficulty level	Moderate (Ateşman)	High School								
Minor surgical procedures										
Nail surgery consent form	57.45	7.94	158	1069	354	3292	9780	7529	6.77	3.08
Overall difficulty level	Moderate (Ateşman)	Elementary (Bezirci-Yılmaz)								
Drug applications										
Methotrexate patient information	30.16	17.01	27	436	131	1373	3787	3216	16.15	3.15
Overall difficulty level	Difficult (Ateşman)	Academic (Bezirci-Yılmaz)								

Discussion

New medical, cosmetic, and surgical interventions are discovered and approved daily in dermatology and cosmetology. Thus, numerous alternative treatments and procedures are offered to patients and physicians for either the treatment of a disease or aesthetic enhancement. The increasing number of alternatives has also led to a rise in potential complications.

Even though the interventions performed during the treatment process may comply with the rules and standards, a failure by a physician to inform a patient of potential complications may result in a malpractice lawsuit [2]. A study examining Supreme Court rulings on informed consent in alleged medical malpractice cases revealed that informed consent was obtained in 46% of the cases, not obtained in 32.9%, not investigated by the court in 19.7%, and in 1.3% of the cases, the informed consent document was found to be falsified [2]. It is insufficient for the physician and the patient to simply sign a written consent form related to the intervention. Dermatologists are responsible for accurately preparing ICFs for the medical, cosmetic, and surgical interventions they perform on their patients and managing the process effectively. In obtaining informed consent, it is essential to consider factors such as gaps in education levels, health literacy, and language barriers [4]. The ICFs used in healthcare institutions are generally inadequate [13,14]. The absence of informed consent for minimally invasive cosmetic procedures (such as soft tissue filler, cosmetic injections, laser treatments, and chemical peeling/dermabrasion) has led to numerous malpractice lawsuits [15,16]. In cases of alleged malpractice, out of 19 expert reports, 13 (68.4%) stated that informed consent was appropriate, while 6 (31.6%) noted that informed consent had not been appropriately obtained. The physician was ordered to pay compensatory damages in 4 cases where informed consent was not appropriately obtained [2].

ICFs should be easily readable and comprehensible to everyone. Readability indices provide numerical data about texts, offering insight into their comprehensibility [17]. In this study, the readability levels of the ICFs on the official website of the Turkish Dermatology Association were determined using the Bezirci-Yılmaz and Ateşman readability formulas developed for Turkish [9,10,12]. The mean readability of all ICFs was at the high school level according to the Bezirci-Yılmaz formula and at a moderate difficulty level according to the Ateşman formula. The ICF with the lowest readability index was the 'Methotrexate' ICF, which was classified at an academic level according to the Bezirci-Yılmaz formula and complicated according to the Ateşman formula. The ICF with the best readability index according to the Bezirci-Yılmaz formula was the "Local PUVA Phototherapy" ICF, with a readability level corresponding to elementary education. According to the Ateşman formula, the ICF with the best readability index was the 'Skin Prick Test' ICF, which had a moderate readability level. When the ICFs were examined as groups, the 'Cosmetic Procedures with Energy-Based Devices' and 'Superficial Skin Renewal Methods' ICFs

were at the undergraduate level according to the Bezirci-Yılmaz formula, while the 'Needle-Injection Cosmetic Procedures', 'Phototherapy Applications', and 'Allergy Testing Applications' ICFs were at the high school level. To comprehend the ICFs, patients should be written at an 8th-grade level or lower, as recommended by patient education experts, or at a 6th-grade level or lower, as the American Medical Association suggested [8,18]. Among the ICFs on the official website of the Turkish Dermatology Association, only the 'Nail Surgery' and 'Local PUVA Phototherapy' ICFs were suitable according to the recommendations of patient education experts, and none of the ICFs met the recommendations of the American Medical Association [8]. According to data from the Turkish Statistical Institute (TÜİK), the mean duration of education for the population aged 25 and over in Türkiye was 9.2 years as of 2022 [19]. Despite the absence of recent studies on health literacy in Türkiye, a study conducted in 2009-2012 revealed that 24% of the Turkish population exhibited inadequate health literacy, while 40.1% demonstrated limited health literacy. Since health literacy enables individuals to enable individuals to make appropriate decisions regarding their health, it should be considered when obtaining informed consent [20].

The readability of a text varies depending on both text-related and reader-related factors. Sentence length, word order, word length, the number of syllables per word, the use of specialized terminology, and difficult words are all text-related factors. The Ateşman formula indicates that the mean sentence length in Turkish is 9-10, while the Bezirci-Yılmaz formula estimates it at 10-11 words. Both formulas suggest that the mean word length in Turkish is 2.6 syllables [9,10]. The mean number of words per sentence in the ICFs on the Turkish Dermatology Association's official website was 10.00 ± 2.49 , consistent with the mean sentence length determined by Bezirci-Yılmaz and Ateşman. However, the mean number of syllables per word in the ICFs was 2.93 ± 0.35 , which exceeds the mean syllable count suggested by Bezirci-Yılmaz and Ateşman. The seven groups had no statistical difference in the mean number of syllables per word. Still, there was a statistically significant difference in the mean number of words per sentence between the groups. The 'Drug Applications (Methotrexate)' ICF had the highest mean number of words per sentence, followed by the 'Cosmetic Procedures with Energy-Based Devices' ICFs.

In Türkiye, the readability of ICFs for common surgical procedures in otorhinolaryngology and head and neck surgery was evaluated as moderately challenging using the Ateşman formula. For otology-related ICFs, the Bezirci-Yılmaz formula indicated that the readability was at a high school level, whereas other consent forms were rated at an elementary school level [21]. A study evaluating the readability of anesthesia consent forms utilized in anesthesiology departments throughout Türkiye revealed that, according to the Ateşman formula, the university consent forms were classified as highly challenging to read. At the same time, those from other institutions were categorized as difficult [22].

Research analyzing the readability of ICFs for elective urology surgeries and emergency medical treatments in Türkiye revealed that the forms for elective procedures were harder to understand. However, according to the Ateşman formula, both groups' consent forms exhibited moderate readability difficulty, while the Bezirci-Yılmaz formula rated them at a high school reading level [23]. A study examining 45 intravenous and intramuscular injection consent forms from various hospitals in Türkiye found that, on average, the readability level was moderately difficult according to the Ateşman formula. Based on the Bezirci-Yılmaz formula, the average readability was equivalent to a secondary education level. No statistically significant differences in readability levels were detected between the hospitals [24]. A comparative analysis of our study with other research conducted within the country reveals that the average readability levels of ICFs commonly utilized in dermatology and cosmetology generally align with a high school reading level, indicating moderate difficulty. Nevertheless, when evaluated using the Bezirci-Yılmaz formula, the ICF on 'Methotrexate' was classified at an academic level. At the same time, the ICFs on 'Cosmetic Procedures with Energy-Based Devices' and 'Superficial Skin Renewal Methods' were rated at an undergraduate level. The findings of our study, in conjunction with those of other studies conducted in our country, indicate that although the readability levels of ICFs are generally comparable according to the Bezirci-Yılmaz and Ateşman formulas, there are some discrepancies [21-24]. It has been determined that readability formulas developed for Turkish can give inconsistent results with each other and with the grade levels of textbooks, leading to the recommendation to create a functional readability formula that prioritizes comprehension [25]. Despite certain inconsistencies and shortcomings, it is recommended that readability formulas be employed to ascertain the comprehensibility of texts [17]. Despite the legal obligation of physicians and other healthcare providers to obtain informed consent, a study has demonstrated that the use of consent forms can significantly increase patient anxiety [26]. Therefore, when preparing an ICF and obtaining consent, care should be taken to avoid increasing the patient's anxiety.

A notable strength of our study is that it represents the first readability assessment conducted within the field of dermatology. The consent forms in our study are those recommended by the Turkish Dermatology Association. The limitation of our study is that different consent forms are used in dermatology clinics.

Conclusion

- The ICFs used in dermatology and cosmetology on the official website of the Turkish Dermatology Association should be revised considering the issues mentioned in this paper. We recommend prioritizing the revision of the 'Methotrexate,' 'Cosmetic Procedures with Energy-Based Devices,' and 'Superficial Skin Renewal Methods' ICFs.
- Considering the increasing number of Arabic-speaking refugees receiving healthcare services in our country, it is

recommended that ICFs be prepared in the native language of these patients to prevent potential lawsuits in the future.

- Dermatologists should ensure that ICFs are readable and comprehensible while avoiding content that may increase patient anxiety.
- To prepare ICFs that meet the most suitable standards for patients and physicians, technical support should be sought from language experts, communication specialists, psychologists, psychiatrists, and educators.

Conflict of Interests

The authors declare that there is no conflict of interest in the study.

Financial Disclosure

The authors declare that they have received no financial support for the study.

Ethical Approval

This study received approval (No. 01.07.2024/12) from the Clinical Research Ethics Committee of Kahramanmaraş Sütçü İmam University.

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