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Informed consent research at a tertiary hospital: How impactful is competency in simpler versus standard consent forms for intravitreal injection therapy?

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Abstract

Aim: To compare the impact of competency in intravitreal injection therapy (IVIT)-related simpler versus standard consent forms (CFs).

Material and methods: Four hundred patients scheduled for IVIT in a tertiary hospital were enrolled between April 1, 2022 and June 30, 2022. These patients were eligible for the study if they had their first IVIT in one eye; those scheduled for IVIT in the other eye were not. Data, including age, gender, educational level, whether the patient was admitted alone or with a companion, and prior IVIT status were collected. A trained clinic secretary first gave the patients the commonly used standard CFs, followed by simpler CFs.

Results: The mean age was 66.10±9.90 years. 93.80% had previously received IVIT. 53.80% of the patients consented on their own. While 98.00% consented without reading standard CFs, 56.00% consented after reading simpler CFs ($p<0.001$). The need for IVIT-related extra information and the desire against having IVIT were significantly higher in simpler than standard CFs ($p<0.001$). 5.00% of those who approved IVIT without reading both forms were illiterate, and 29.20% had vision issues. The probability of simpler CF reading increased by 4.653 and 7.510 times in high school and university graduates, respectively, relative to primary school graduates.

Conclusion: Simpler CFs had a much higher reading rate, which was linked to a higher rate of patients opting against IVIT. In medical fields like ophthalmology, where many procedures and research are performed, ethically approved informed consent requires consideration of patients' education and prior treatment experience.

Key words: consent forms, educational level, ethics, intravitreal injection therapy, readability

Introduction

Informed consent is not only a legal requirement. It also entails a moral and ethical obligation to safeguard a patient's right to shared decision making. This procedure refers to a discussion between patients, physicians, and/or researchers that ultimately results in the patient's approval to undergo a specific therapeutic procedure or participate in a clinical research [1]. In clinics, consent forms (CFs) are frequently not clearly prepared. This is primarily due to the fact that researchers, physicians, and consenting patients frequently regard these documents as an unnecessary procedural component. These forms are typically prepared by physicians performing a specific procedure to fulfill their legal responsibilities, and hence signing the CFs by patients may absolve the physician from legal liability. Nonetheless, preparing an insufficiently appropriate CF indicates a failure to meet ethical responsibilities. What is legal is not always

what is ethical, and physicians must abide by both the law and professional ethics principles [2-4].

In clinical studies and before any therapeutic interventional procedure, obtaining informed consent is critical. Nevertheless, it has always been questioned whether or not the procedures is totally understood by patients. The patients' competence, the amount of information and understanding they require, and, most importantly, whether they truly and voluntarily consent to the procedure have long been contested [5]. The possibility that patients were not adequately informed about the procedure before participating in a study or having a therapeutic procedure could have serious ethical ramifications. Given the lower educational level (EL), particularly in developing countries, CFs should be prepared in much clearer and more readable language, and the informed consent process should be handled much more delicately [6,7]. The term *"readability"* is used to describe the EL for which a particular text is written. Consent forms should be written in a way that low-education patients can easily read and understand [8].

Intravitreal injection therapy (IVIT) is a common interventional procedure performed in ophthalmology clinics for different indications, including age-related macular degeneration (AMD) [9], retinal vein occlusion (RVO) [10], diabetic retinopathy (DR) [11], etc. Around 170 million people worldwide suffer from AMD-related vision loss, with that figure expected to rise to 288 million by 2050 [12,13]. It is estimated that 28 million people worldwide suffer from RVO [10]. Besides, a global prevalence of DR is expected to reach 191 million by 2030 [11]. Intravitreal injection therapy is also used to treat cystoid macular edema secondary to uveitis, Irvine-Gass syndrome, and retinitis pigmentosa [14-16].

The current study sought to determine the impact of competency in IVIT-related simpler versus standard CFs. In this context, the rate of reading simpler CFs prepared according to lower EL, the relationship of EL with CF reading behaviors, and the impact of simpler CFs on the decision-making behavior of the patients were compared to standard CFs.

Material and methods

This single-centered comparative study enrolled 400 patients who were recommended for IVIT after being examined in a tertiary hospital at the Afyonkarahisar Health Sciences University Faculty of Medicine Department of ophthalmology between April 1, 2022 and June 30, 2022. The study protocol adhered to the Declaration of Helsinki's ethical principles and received full approval from the institutional review boards of Afyonkarahisar Health Sciences University Ethics Committee with approval ID: 2022/278. All patients who agreed to take part in the study were informed about it and consented.

The patients were eligible for the study if they received IVIT for the first time in one eye. Those who were scheduled for IVIT in the contralateral eye were not included in the study again. Demographic details such as age, gender, and EL were collected, as well as whether the patient was admitted to the hospital alone or with a companion. In cases where there were companions, their closeness to the patient was determined. After determining whether the companion was the participant's child, spouse, distant relative, or caregiver, the data was divided into subgroups for descriptive statistics. Participants were also asked if they had received IVIT at another medical facility.

Intravitreal injection therapy-related standard CFs, which are routinely used in our ophthalmology clinic, were analyzed using the Bezirci-Yilmaz [17] and Ateşman [18] readability formulas, which have been proved to be reliable for Turkish, the local language in which the form was prepared. As a result, the Bezirci-Yilmaz readability formula yielded a readability with the EL of approximately 13 years, while the Ateşman readability formula yielded a readability with the EL of approximately associate degree level (13-14-15 years). On the other hand, the Bezirci-Yilmaz and Ateşman readability formulas determined that the new, simpler CFs in an easier-to-read format for the patients were readable with 7 years and 9-10 years of ELs, respectively.

At first, a trained clinic secretary distributed the commonly used standard CFs to the patients under the direction of an experienced ophthalmologist (HHG). This was followed by determining whether the patients had completely read CFs and confirming once more by asking whether they had read CFs immediately after signing the forms. Simpler CFs were then distributed to patients and/or companions. In the event that the companions read CFs, they were also asked about their EL, and the data was recorded. Testing was performed to determine whether simpler CFs were completely read, and again, confirmation of the reading was performed after signing the forms. After reading simpler CFs, patients were divided into three groups: a) those who approved the IVIT, b) those who needed IVIT-related extra information before approving, and c) those who decided against IVIT. Analysis was then performed in conjunction with the demographic characteristics of the patients.

Statistical analysis

Statistical analysis was carried out using Predictive Analytics SoftWare (PAWS) Statistics version 18 (SPSS Inc., version 18.0, Chicago, IL, USA). Categorical variables were represented as percentages and frequencies in the descriptive statistics results, while continuous variables were represented as mean and standard deviation. To compare categorical variables in independent groups, the Chi-Square and Fisher Exact tests were used; in dependent groups, the McNemar test was used. Univariate and Multivariate Logistic Regression tests were used to evaluate variables that had statistically significant differences. The results of logistic regression were presented as odds ratios (OR) and 95% confidence intervals (95% CI). A $p<0.05$ was accepted as the statistical significance level.

Results

The study included 400 patients, with females accounting for 51.00%. The mean age was 66.10±9.90 years with 53.80% of the patients being over 65.70% had primary school education. Over 93% had previously received IVIT. The majority of patients (53.80%) were found to be alone while consenting. 56.5% of those who signed CFs had primary school education. Table 1 summarizes the patients' demographic characteristics.

In terms of standard CF reading rates, 98.00% consented without even reading CFs, and only 2.00 % read them completely. Simpler CFs, on the other hand, were read completely by 56.00%, and partially by 4.50% of the participants who were evaluated alongside those who did not read CFs at all. A comparison of standard CF reading rates with those of simpler CFs revealed that the latter were associated with statistically significantly higher reading rates ($p<0.001$) (Table 2).

Standard CFs were read significantly more frequently by the first IVIT recipients (16%) than by prior IVIT recipients (1.10%) ($p=0.001$). Simpler CFs had higher reading rates in both groups, with first IVIT recipients having the highest reading rates (68.00%) compared to prior IVIT recipients (52.20%),

Table 1 Demographic characteristics of the patients receiving IVIT

Parameters	*n (%)*
Educational level	
Illiterate	42 (10.50)
Literate	11 (2.70)
Primary school	280 (70.00)
High school	35 (8.80)
University	32 (8.00)
Signers	
Him/herself	215 (53.80)
Children (Son, Daughter)	92 (23.00)
Spouse	48 (12.00)
Others	45 (11.20)
Educational level of the signers	
Illiterate	20 (5.00)
Literate	2 (0.50)
Primary school	226 (56.50)
High school	74 (18.50)
University	78 (19.50)
First time IVIT	
Yes	25 (6.20)
No	375 (93.80)

n: Number of participants, %: Percent, IVIT: Intravitreal injection therapy

though this difference was not statistically significant (p=0.212). 83.00% of those who read simpler CFs changed their prior consent decisions for the procedure and eventually approved it. However, before approving, 15.60% asked IVIT-related extra questions. 1.30% decided against having IVIT. Compared to standard CF readers, the need for IVIT-related extra information and the desire against having IVIT were found to be statistically significant based on simpler CFs (p<0.001) (Table 3).

5.00% of the patients who consented to IVIT without reading both forms were illiterate, and 29.20% had vision problems that made it difficult to see clearly. Thus, both of these variables were identified as absolute risk factors for failing to read CFs. After excluding 137 patients, logistic regression analysis was performed, taking into account their ELs and prior IVITs. In comparison to primary school graduates, the likelihood of simpler CF reading increased by 4.653 times in high school graduates and 7.510 times in university graduates. Receiving IVIT for the first time was found to be a non-significant factor. The likelihood of reading simpler CFs increased 4.652 times in high school graduates and 7.536 times in university graduates, according to multivariate logistic regression analysis, and receiving the IVIT for the first time was revealed to be a non-significant factor once more (Table 4).

Table 2 Comparative analysis of the respective CF reading rates among patients receiving IVIT

		Simpler CFs		Total n, (%)	P value
		Didn't read, n (%)	Read, n (%)		
Standard CFs	Didn't read, n (%)	176 (44.00)	216 (54.00)	392 (98.00)	<0.001
	Read, n (%)	0 (0)	8 (2.00)	8 (2.00)	
Total n, (%)		176 (44.00)	224 (56.00)	400 (100.00)	

n: Number of participants, %: Percent, IVIT: Intravitreal injection therapy, CF: Consent form

Table 3 Comparative analysis the patients' pre-IVIT preferences based on simpler CFs

	Simpler CFs		Total n, (%)	P value
	Didn't read, n (%)	Read, n (%)		
Decided against IVIT	0 (0.0)	3 (1.3)	3 (0.8)	<0.001
Asked extra questions, approved	0 (0.0)	35 (15.6)	35 (8.8)	
Approved without asking	176 (100.0)	186 (83.0)	362 (90.5)	
Total n, (%)	176 (100.0)	224 (100.0)	400 (100.0)	

n: Number of participants, %: Percent, IVIT: Intravitreal injection therapy, CF: Consent form

Table 4 Analysis of simpler CFs based on ELs in first-time and multiple IVIT recipients using logistic regression

	B	SE	Wald	P value	OR	95% CI for OR	
						Lower	Upper
Univariate							
Primary school*							
High school	1538	0.556	7.65	0.006	4.653	1.565	13.833
University	2.016	0.624	10.443	0.001	7.510	2.211	25.512
First-time IVIT**	0.545	0.441	1.526	0.217	1.725	0.726	4.094
Multivariate							
Primary school*			16.206	<0001			
High school	1.537	0.556	7.647	0.006	4.652	1.565	13.829
University	2.020	0.624	10.464	0.001	7.536	2.216	25.620
First-time IVIT*	-0.110	0.682	0.026	0.872	0.896	0.235	3.409

**Taken as a reference, ** Multiple IVITs were taken as reference, IVIT: Intravitreal injection therapy, CF: Consent form, EL: Educational level, SE: Standard error, OR: Odds ratio, CI: Confidence of interval*

Discussion

Informed consent has a long history in different fields, including medicine, moral philosophy, and the law. It is inextricably linked to philosophical ideas such as personhood and individual self-determination [19-21]. In daily clinical practice, having obtained patient informed consent is highly essential. Informed consent in human research, on the other hand, presents a unique set of challenges, almost always as a result of the study design regarding specific interventional procedure. Patients should completely understand the procedure during informed consent process, which is an ethically acceptable principle that applies to both clinical interventional procedures and research. This is because, in order to participate in any research or therapy, patients must make conscious decisions based on rational information. Consent forms should be composed in such a way that participants can easily read and comprehend the entire procedure, including all potential risks [2-4]. As CFs have profound and beneficial practical and moral implications for clinical practice, the risk-management elements of CFs should not be underestimated. In terms of ethics, a physician's responsibility to disclose is more of a necessity for individual autonomy than the primary goal of CFs [21].

In the ophthalmology field, as in all other medical fields, an appropriate informed consent process is required before any particular research or therapy. It is widely accepted that when an individual signs CF, he or she is indicating acceptance. Signing CF without being extensively informed about a particular research or therapy, on the other hand, does not imply that an individual voluntarily and truly consents, nor does it mean that ethical responsibilities have been fulfilled [22]. This condition was essentially evidenced in the current study, which found that, when compared to standard CFs commonly used in clinical practice, the simpler and more understandable the CFs, the higher the rate of reading and, as a result, the higher the rate of decision against IVIT among patients who were recommended for this therapy. Moreover, patients who are receiving multiple doses of the same therapy are more likely to voluntarily consent without even reading CFs repeatedly. This was also the case in the current study, which found that patients who received multiple IVITs were less likely to read simpler CFs. Despite this, the logistic regression analysis determined that the condition was not significant and that the patients' EL and CF readings were closely related.

Five components of valid informed consent are voluntarism, capacity, disclosure, comprehension, and decision [23]. Patients must be free of "coercion, unfair persuasions, and inducements" in order to be voluntary participants [24]. The ability of a patient to make health-care decisions is described as *capacity*. A related concept is *competence*, which refers to the patient's legal standing to make health-care decisions. *Disclosure* entails providing a patient with comprehensive information about a specific therapeutic procedure, including its goal and basic features, in addition to its risks, potential benefits, and available options. Despite the fact that there is barely any agreement in law or ethics concerning what constitutes adequate *understanding*, this condition necessitates that the patient comprehend the information provided and recognize its applicability to his or her specific situation. The term *decision* refers to the patient's permission for the specific therapy to be performed by a physician [19,23]. Although CFs aid in the facilitation and documentation of this permission, they should be perceived as supplementary to the process by which the patient and researcher or physician talk and negotiate the particular research or therapy.

As far as EL was concerned, the current study revealed that the majority of EL among patients was primary school education, which was also found in more than 56.00% of CF signers. High school education increased the likelihood of simpler CF reading by 4.653 times relative to primary school education, while university education increased it by 7.510 times. Furthermore, 5.00% of the patients who consented to IVIT without reading both CFs were illiterate, and more than 29.00% had vision issues that made it impossible for them to read CFs. All of these patients stated that they had previously undergone IVIT; however, it is unclear whether they had companions to assist them with CF reading and comprehension during prior IVITs. As explained previously [23], whether or not these patients have previously undergone the same procedure, there may be ethical implications to performing an interventional procedure based on informed consent without the opportunity to extensively read and understand CFs.

It is reasonable to anticipate that the patients' visual acuity will be inadequate, particularly before undergoing ophthalmological interventional procedures. If necessary, larger-font CFs could be ethically useful for these patients. Fundamentally, patients have the right to be informed about all IVIT-related risks [9,23], so alternative measures that leverage current technological advancements should be considered for patients with vision issues. For conditions where hearing is not an issue, the written consent text could be presented as an audio recording. Likewise, obtaining an informed CF before cataract surgery using video has been shown to increase patient satisfaction while also shortening the consent process [25]. In the event that these resources aren't available, the importance of preparing CFs in a more readable and understandable manner increases dramatically.

The fact that CFs are usually not read carefully enough, or that patients who do read the form completely are unaware of the IVIT-related risks, appears to be a point of contention in the medical community. One study found that 69.00% of patients who received IVIT were unaware that endophthalmitis could develop secondary to the procedure [26]. Endophthalmitis, one of the most serious IVIT-associated complications, may be unknown to the patients on whom the procedure will be performed, which could be an ethically unacceptable situation. Another study found that converting CFs that could be read with an average of ten-year education into CFs that could be read with a seven-year education increased reading by about 6.5 times [27]. Likewise, in the current study, simpler CFs that could be read with an eight-year education were prepared to replace standard CFs commonly used in clinical practice that could be read with a 16-year education, and the former were eventually found to be associated with a 28-fold higher reading rate. It should be noted that the patients' attention might have been drawn in this direction while simpler CFs were being distributed, which could explain the significantly increased CF reading rate. This is possible despite the fact that no instructions were provided during the consent process, which could have influenced their reading behaviors and, as a result, the IVIT-related final decisions. Attempts should be made during the informed consent process to reduce patients' therapeutic misunderstanding.

The current study does have some limitations. The time required for the entire IVIT-related consent process was not considered because all participants were not given a time limit to make their final decision with respect to this therapy. Giving patients more time to consider participating has been linked to a significantly increased patient comprehension [28].

The experienced ophthalmologist oversaw the distribution of CFs by a trained clinic secretary. Regardless, discrepancies in CF distribution between the earlier and later learning periods of the study could have contributed to data bias. Essentially, informed consent is inextricably linked to the deontological concept of personhood; however, it also serves a critical and positive contribution to medicine. This can lead to improved patient-physician interactions, the physician having a better understanding of the patient's disease, and the patient complying to therapy. Nonetheless, the informed consent framework has some flaws that should be addressed. Even though informed consent improves physician-patient interaction and decision-making, it cannot foster autonomy when such options are unavailable. Additionally, since informed consent evolved in a particular societal perspective, it may not be universally applicable to all societies or cultures [29].

In comparison to past studies on informed consent process, the current study has a great advantage in that it included a significantly larger number of patients. Consequently, it provides clinically useful evidence-based findings from an ethical perspective that extends beyond the field of ophthalmology. It also paves the way for large-scale multi-racial and multi-lingual studies to investigate this extremely sensitive subject when it comes to fully reading and comprehending CF before participating in any research or therapy.

Conclusively, simpler CFs had a much higher reading rate, which was associated with a higher rate of decision against IVIT among patients recommended for this therapy. Patients who had previously received IVIT had a lower probability of reading simpler CFs. Despite having previously undergone the same procedure, there may be ethical implications in performing an interventional procedure based on informed consent without the opportunity to thoroughly read and understand CFs. In medical fields such as ophthalmology, where many interventional procedures and clinical research are performed, obtaining CFs in accordance with ethical principles is critical, especially when patients' ELs and prior treatment experience are considered.

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