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Do Our Patients Read Informed Consent Forms?

Hastalarımız Bilgilendirilmiş Onam Formlarını Okuyor mu?

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ABSTRACT Objective: The patient's informed consent is consent to the doctor in the light of knowledge of possible consequences, risks and benefits of the procedure to be performed. The information is shared with the patient on a completely honest and factual basis. In Turkey, according to article 24 of the patient rights regulation; every medical intervention in which the person/legal guardian do not have the consent, or is present in a missing or incorrect manner is against the law. In the present study, the status of reading informed consent forms of patients who applied to Oral and Maxillofacial Surgery Unit was investigated. **Material and Methods:** This study investigates informed consent reading rates of 134 patients/legal guardians who admitted to the Oral and Maxillofacial Surgery Unit between April 2018-January 2019, for various procedures. After the patients had been informed by the physicians about the operations, informed consent forms were given to read and sign. Following the signatures, demographic data, type of the operation, reading status and reasons for not reading were noted. **Results:** Only 31 patients read the informed consents fully, 18 read them partially, and 85 signed them without any reading. Too long consent forms, emergence of fear and trust in doctors were the reasons for not reading. The results suggested that the patient's initial reaction was not to read the informed consents, independently from demographic data, operation severity, educational background and working status. **Conclusion:** It will be in the best interest of both the doctor and the patient to perform the procedure correctly and completely. It is obligatory that institutions audit and report informed consents readings and according to results, improve institutional procedures.

Keywords: Bioethics; ethics; informed consent; jurisprudence; surgery; surveys

ÖZET Amaç: Hastanın bilgilendirilmiş onamı, yapılacak işlemin olası sonuçları, riskleri ve yararları bilgisi ışığında hastanın doktora verdiği izindir. Bilgiler hasta ile tamamen dürüst ve eksiksiz bir şekilde paylaşılmalıdır. Türkiye'de hasta hakları yönetmeliğinin 24. maddesine göre; şahıs/yasal vasinin rızası olmadığı veya eksik veya yanlış bir şekilde bulunduğu her tıbbi müdahale kanuna aykırıdır. Mevcut çalışmada, Oral ve Maksillofasiyal Cerrahi Ünitesine başvuran hastaların bilgilendirilmiş onam formlarını okuma durumları araştırılmıştır. **Gereç ve Yöntemler:** Bu çalışmada, Nisan 2018-Ocak 2019 tarihleri arasında Oral ve Maksillofasiyal Cerrahi Ünitesine çeşitli prosedürler için başvuran 134 hasta/yasal vasinin bilgilendirilmiş onam okuma oranları araştırılmıştır. Doktorların operasyonlar hakkında bilgi vermelerini takiben hastalara okumaları ve imzalamaları için bilgilendirilmiş onamlar verilmiştir. İmzaların ardından demografik veriler, operasyon ciddiyeti, okuma durumu ve okumama nedenleri kaydedilmiştir. **Bulgular:** Sadece 31 hasta bilgilendirilmiş onamları tamamen okurken, 18 tanesi kısmen okumuş, 85 kişi ise okumadan imzalamıştır. Çok uzun onam formları, formların korku oluşturması ve doktorlara duyulan güven, okumama nedenleri olarak bildirilmiştir. Sonuçlar, hastaların ilk tepkisinin demografik verilerden, operasyon şiddetinden, eğitim geçmişinden ve çalışma durumundan bağımsız olarak bilgilendirilmiş rızaları okumamak olduğunu göstermiştir. **Sonuç:** Prosedürün doğru ve tam olarak yapılması hem doktorun hem de hastanın yararına olacaktır. Kurumların bilgilendirilmiş onam formlarının okunma durumlarını takip etmesi, raporlaması ve sonuçlara göre kurumsal prosedürleri iyileştirmesi zorunludur.

Anahtar Kelimeler: Anketler; aydınlatılmış onam; biyoetik; cerrahi; hukuk; etik

In recent years, the increase in the number of medico-legal cases and the growing demand of patients to have a say in their treatment have lent considerable importance to the issue of informed consent.[1] To be able to protect themselves and to ensure their autonomy; patients need to be able

to decide on the treatment process by receiving the information they need.[1,2] Access to this information can be obtained from the doctor or nurse, but also from friends or relatives who have undergone a similar procedure and from the media and/or internet.

At the heart of the informed consent procedure is shared decision-making. It is an opportunity for the medical team to guide the patient to make the right decision for him- or herself and at the same time eliminate unrealistic expectations about the procedure. In addition, it creates a relationship of openness and trust that can help when undesirable complications related to the surgical procedure are encountered.[1] Disclosure is fundamentally made by the surgeon in detail during the informed consent procedure, and the importance of this procedure both for the patient and the doctor should be emphasized.

A common misunderstanding among healthcare personnel is that a signed informed consent form proves true consent. An unaccompanied signed consent form may not confirm that true consent was obtained from the patient. It simply documents a single stage of the informed consent procedure. For a patient to be truly informed, he or she must understand the information that the doctor has disclosed. This is established through a mutual consultation during which the doctor must consider the patient's current understanding of his or her condition and the proposed treatment plan, the patient's overall capacity to understand, and the cultural considerations that may affect the patient's decision-making. The task of the patient in this relationship is to try to understand the information given and ask questions on unclear issues so that he or she undergoes the operation free of questions or concerns.

Because many patients may not have a full understanding of the procedures they will undergo, it is very difficult for the doctor to be confident about the adequacy of the patient's consent. Therefore, strict adherence to the principles of informed consent requires that a doctor disclose just enough information about the risks and benefits of the proposed treatment so that the patient becomes adequately informed and is able to contribute in shared decision-making. However, a practicing physician may find it difficult to determine the threshold between an excessive and insufficient amount of information.

MATERIAL AND METHODS

The study was approved by Ankara University, Faculty of Dentistry, Institutional Review Board (approval number, 08/07; clinical trial registration no. NCT 03555760) and was conducted in accordance with the Declaration of Helsinki.

All patients admitted for surgery, including those accompanied by legal guardians, between April 2018 and January 2019 were enrolled in the study. The surgical procedures differed and are described below. Verbal information was provided and the consent procedures were performed by the senior surgeon and anaesthesiologist. Patients were not notified about the study before they read the informed consent form, in order to eliminate changes in their reading (i.e., reading status). Some surgeons gave their patients the consent form on the day before surgery, which allowed the patients to read it at home, and other surgeons provided the form on the day of surgery. All patients were directed to read the informed consent materials and ask any questions that came to mind. The informed consent materials consisted of two parts-one for the surgical procedure and the other for the anaesthetic intervention. The consent forms were prepared based on content guidelines set by the Republic of Turkey Ministry of Health and differed in length according to the procedure. The estimated reading time was 30 min. Written informed consent forms concerning the study were given by the authors.

After the patient had agreed for participation in the study, information on his or her reading status and demographic data were collected. If the patient admitted to not having read the consent forms, the surgeon was notified. All 134 patients (65 males and 69 females) agreed to participate in the study. Data on reading status, reasons for not reading, age, educational background (EB), work

status (WS), operation severity (OS) and when the consent procedure took place were collected.

Demographically, the patients or their legal guardians were classified into three age groups: A1 (ages 18-25 years), A2 (ages 26-64 years), and A3 (ages 65 years and above); six EB groups: EB1 (illiterate), EB2 (primary school graduate), EB3 (middle school graduate), EB4 (high school graduate), EB5 (university graduate), and EB6 (doctorate holder); and five WS groups: WS1 (working), WS2 (not working), WS3 (student), WS4 (retired), and WS5 (unemployed).

Operation severity was classified as follows: OS1, iliac bone harvesting and jaw reconstruction, jaw fracture, bimaxillary, sagittal split, and Le Fort osteotomies, temporomandibular joint surgeries, and all minor procedures; OS2, cysts of the jaws, osteomyelitis, salivary gland excisions, and bone grafting procedures; and OS3, impacted tooth extractions, salivary gland sialoliths, lipomas of the facial soft tissue, fat harvesting and grafting, sinus augmentations, and full-mouth dental implant procedures. Operation severity levels decreased from OS1 to OS3.

The data were analysed by using SPSS for Windows (ver. 11.5; IBM Corporation, Armonk, NY, USA). Descriptive statistics are reported as the number of cases (n) and as percentages (%). Nominal variables were evaluated by using Pearson's chi-squared or Fisher's exact test. A p-value <0.05 was considered to indicate statistical significance.

RESULTS

The reading status of the consent forms and the reasons for not reading according to OS and age groups are presented in Table 1 and Table 2. The

TABLE 1: Reading status of consent forms according to operation severity and age groups.

		Operation Severity			Age group			
Reading Status		**OS 1**	**OS 2**	**OS 3**	**A 1**	**A 2**	**A 3**	**Total**
Read	Count	21	5	5	8	23	0	**31**
	% within RS	67.7%	16.1%	16.1%	25.8%	74.2%	0.0%	**100.0%**
Didn't read	Count	45	21	19	17	65	3	**85**
	% within RS	52.9%	24.7%	22.4%	20.0%	76.5%	3.5%	**100.0%**
Partially read	Count	11	6	1	1	17	0	**18**
	% within RS	61.1%	33.3%	5.6%	5.6%	94.4%	0.0%	**100.0%**
Total	Count	77	32	25	26	105	3	**134**
	% within RS	57.5%	23.9%	18.7%	19.4%	78.4%	2.2%	**100.0%**

RS: Reading status; OS 1: Operation severity group 1; OS 2: Operation severity group 2; OS 3: Operation severity group 3; A 1: Age group 1; A 2: Age group 2; A 3: Age group 3.

TABLE 2: Reasons for not reading according to operation severity and age groups.

		Operation Severity			Age Group			
Reason for not reading		**OS 1**	**OS 2**	**OS 3**	**AG 1**	**AG 2**	**AG 3**	**Total**
Too long	Count	19	9	7	6	28	1	**35**
	% within RN	54.3%	25.7%	20.0%	17.1%	80.0%	2.9%	**100.0%**
Scared	Count	9	5	4	4	12	2	**18**
	% within RN	50.0%	27.8%	22.2%	22.2%	66.7%	11.1%	**100.0%**
Trust in doctor	Count	29	13	9	8	43	0	**51**
	% within RN	56.9%	25.5%	17.6%	15.7%	84.3%	0.0%	**100.0%**
Total	Count	57	27	20	18	82	3	**103**
	% within RN	54.8%	26.0%	19.2%	17.3%	79.8%	2.9%	**100.0%**

RN: Reasons for not reading; OS 1: Operation severity group 1; OS 2: Operation severity group 2; OS 3: Operation severity group 3; AG 1: Age group 1; AG 2: Age group 2; AG 3: Age group 3.

reading status did not vary significantly as a function of OS or age (p=0.327 and 0.344, respectively) nor did the reason for not reading the form (p=0.978 and 0.178, respectively).

Table 3 and Table 4 present the reading status of the consent forms and the reasons for not reading according to EB and WS. No significant differences were found in either group with respect to reading status (p= 0.448 and 0.863, respectively) or the reason for not reading the form (p= 0.695 and 0.314, respectively).

The reading status of and reasons for not reading according to adult patients and the legal guardians of minors are presented in Table 5. The differences between the two groups were not significant (p= 0.561 and 0.554, respectively).

The reading status and reasons for not reading also did not differ significantly between patients who received the informed consent form on the day of surgery vs. the day before surgery (p= 0.007 and 0.334, respectively; Table 6).

DISCUSSION

Previous studies have shown that demographic factors, such as lower education levels, are associated with less understanding of informed consent forms.[3] Other demographic factors, such as race, age, sex, and marital status, were also shown to influence the informed consent procedure.[4] However, these demographic factors were investigated for their effect on the outcome of informed consent procedures rather than on the patients' initial

TABLE 3: Reading status according to educational background and working status.

		Educational Background						Working Status					
Reading Status		**EB 1**	**EB 2**	**EB 3**	**EB 4**	**EB 5**	**EB 6**	**WS 1**	**WS 2**	**WS 3**	**WS 4**	**WS 5**	**Total**
Read	Count	0	2	3	14	12	0	16	8	4	0	3	**31**
	% within RS	0.0%	6.5%	9.7%	45.2%	38.7%	0.0%	51.6%	25.8%	12.9%	0.0%	9.7%	**100.0%**
Didn't read	Count	1	17	4	35	23	5	41	25	9	4	6	**85**
	% within RS	1.2%	20.0%	4.7%	41.2%	27.1%	5.9%	48.2%	29.4%	10.6%	4.7%	7.1%	**100.0%**
Partially read	Count	0	3	1	5	8	1	11	3	1	1	2	**18**
	% within RS	0.0%	16.7%	5.6%	27.8%	44.4%	5.6%	61.1%	16.7%	5.6%	5.6%	11.1%	**100.0%**
Total	Count	1	22	8	54	43	6	68	36	14	5	11	**134**
	% within RS	0.7%	16.4%	6.0%	40.3%	32.1%	4.5%	50.7%	26.9%	10.4%	3.7%	8.2%	**100.0%**

RS: Reading Status; EB 1: Educational Background Group 1; EB 2: Educational Background Group 2; EB 3: Educational Background Group 3; EB 4: Educational Background Group 4; EB 5: Educational Background Group 5; EB 6: Educational Background Group 6; WS 1: Working Status Group 1; WS 2: Working Status Group 2; WS 3: Working Status Group 3; WS 4: Working Status Group 4; WS 5: Working Status Group 5; WS 6: Working Status Group 6.

TABLE 4: Reasons for not reading according to educational background and working status.

		Educational Background						Working Status					
Reason for not reading		**EB 1**	**EB 2**	**EB 3**	**EB 4**	**EB 5**	**EB 6**	**WS 1**	**WS 2**	**WS 3**	**WS 4**	**WS 5**	**Total**
Too Long	Count	0	8	1	13	11	2	20	10	3	1	1	**35**
	% within RN	0.0%	22.9%	2.9%	37.1%	31.4%	5.7%	57.1%	28.6%	8.6%	2.9%	2.9%	**100.0%**
Scared	Count	1	2	0	6	8	1	11	4	1	2	0	**18**
	% within RN	5.6%	11.1%	0.0%	33.3%	44.4%	5.6%	61.1%	22.2%	5.6%	11.1%	0.0%	**100.0%**
Trust in doctor	Count	0	10	4	21	13	3	21	14	6	2	28	**51**
	% within RN	0.0%	19.6%	7.8%	41.2%	25.5%	5.9%	41.2%	27.5%	11.8%	3.9%	15.7%	**100.0%**
Total	Count	1	20	5	39	32	6	51	28	10	5	9	**103**
	% within RN	1.0%	19.2%	4.8%	38.5%	30.8%	5.8%	49.5%	27.2%	9.7%	4.8%	8.7%	**100.0%**

RN: Reasons for not reading; EB 1: Educational background group 1; EB 2: Educational background group 2, EB 3: Educational background group 3; EB 4: Educational background group 4; EB 5: Educational background group 5; EB 6: Educational background group 6; WS 1: Working status group 1; WS 2: Working status group 2; WS 3: Working status group 3; WS 4: Working status group 4; WS 5: Working status group 5; WS 6: Working status group 6.

TABLE 5: Reading status and reasons for not reading of legal guardians.

		Reading Status				Reasons for not reading	
		Of age	Under age			Of age	Under age
Read	Count	26	5	**Too Long**	Count	30	5
	% within RS	83.9%	16.1%		%within RN	85.7%	14.3%
Didn't read	Count	71	14	**Scared**	Count	14	4
	% within RS	83.5%	16.5%		%within RN	77.8%	22.2%
Partially read	Count	17	1	**Trust in doctor**	Count	45	6
	% within RS	94.4%	5.6%		%within RN	88.2%	11.8%
Total	Count	114	20		Count	89	15
	% within RS	85.1%	14.9%		%within RN	85.6%	14.4%

RS: Reading status; RN: Reasons for not reading.

TABLE 6: Reading status and reasons for not reading of patients who received the informed consents before hospitalization.

		Reading Status				Reasons for not reading	
		Day of surgery	One day before surgery			Day of surgery	One day before surgery
Read	Count	26	5	**Too Long**	Count	31	4
	%within RS	83.9%	16.1%		%within RN	88.6%	11.4%
Didn't Read	Count	82	3	**Scared**	Count	17	1
	%within RS	96.5%	3.4%		%within RN	94.4%	5.6%
Partially read	Count	14	4	**Trust in doctor**	Count	49	2
	%within RS	77.8%	22.2%		%within RN	96.1%	3.9%
Total	Count	122	12		Count	97	7
	%within RS	91.0%	9.0%		%within RN	93.3%	6.7%

RS: Reading status; RN: Reasons for not reading.

response to reading the consent forms, which was the focus of the present study. We found that demographic factors did not have an effect on the reading status of the informed consent forms, as all patients' initial response was to sign the forms without reading them. This result may have reflected the adequate verbal information provided by the medical team, although we did not evaluate the patients' understanding of the consent forms. Studies of patients' initial response to reading the informed consent forms after having received comparable verbal information from the physician have not been previously conducted.

Topics related to the informed consent procedure that have been addressed in the literature include who should receive the informed consent form, when it should be given, how to present a procedure and its risks and possible benefits, and how to offer alternative treatment options.[1] Anderson and Wearne reported that the best time to receive informed consent was when the patient is initially scheduled for surgery.[1] They suggested that informed consent obtained on the day of surgery, which is the preferred method in the average clinical setting and in our clinic, may cause the patient to make a decision under duress. In our study, a higher percentage of the patients who were sent home with the informed consent form on the day before the operation read the form, although the difference was not statistically significant compared to the patients who received the form on the day of surgery. In the same study, the authors argued that senior staff should be responsible for obtaining informed consent, because junior personnel may provide incomplete information about the surgical procedure and its possible risks

and may not respond satisfactorily to the patients' questions. This could not be investigated in the present study because all written consent procedures were conducted by surgeons with mid-level seniority.

In a study reported by McNutt et al., patients were monitored by a physician while reading the informed consent material.[5] The authors concluded that the observing physicians did not accurately assess patients. For example, for patients who did not fully read the form, the physicians concluded that they had 'fully read' it. In the present study, the patients were asked whether or not they had read the form. Although this was not an objective measure, the "I didn't read" responses from the vast majority of patients suggested that they responded honestly.

However, even patients who read the informed consent form may not be properly informed. Whereas the importance of patients understanding what they are reading is well-recognised, there is no consensus on how to measure correct understanding.[6] Similarly, a weakness of the present study was that it did not evaluate patient understanding of the informed consent materials. Thus, in future studies, tools such as the Digitised Informed Consent Comprehension Form should be used to measure patient understanding.[7] Agre and Rapkin investigated the effect of informed consent tools, including written and online materials, videos, and booklets, on patient understanding of informed consent.[2] They found that the provision of different media tools did not result in higher patient information status than that of patients informed using routine written tools. They concluded that rather than providing excessive details that cover many pages, the content requiring patient approval should only contain important information and be accompanied by appropriate resources that provide more comprehensive information. The guidelines developed by the U.S. Food & Drug Administration for obtaining informed consent recommend that the materials contain very detailed basic elements, such as a description of the clinical procedure; its potential risks, discomforts, and benefits; alternative procedures or treatments; and information on confidentiality, compensation, medical treatments in the event of injury, contacts, and voluntary participation.[8]

CONCLUSION

In the present study, informed consent reading rates were low-only 31 of the 134 patients reported that they had read the forms fully. The reading status of the consent forms and reasons for not reading did not vary as a function of OS, age, EB, or WS, nor did they differ between legal guardians consenting for minors and adult patients, or between patients who received the informed consent form on the day before or on the day of surgery. The institutional measures taken to ensure the effectiveness of the consent form procedure should be tested regularly, revising them on a regular basis as needed.

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

All authors contributed equally while this study preparing.

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