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ASSESSMENT OF INPATIENTS IN TRAKYA UNIVERSITY HOSPITAL IN TERMS OF INFORMED CONSENT INDICATED BY MINISTRY OF HEALTH'S PATIENT RIGHTS REGULATIONS

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ABSTRACT

Aims: The informed consent constitutes the legal validity of any medical intervention and treatment, and it provides the patient with information about the procedure. In this study, we aimed to assess the extent informed consent is being applied in Trakya University Hospital in accordance to Ministry of Health's regulations.

Methods: A data collecting form has been prepared with respect to Ministry of Health's relevant regulations and it was applied to 78 inpatients. The form consists of 18 two-point statements and 4 questions towards the patient's demographic profile. As for descriptive statistics, numbers and percentages have been used for the statements, thus arithmetic mean ± standard deviation (minimum-maximum) has been used for the questions, respectively.

Results: Out of all included patients, 47 (60.3 %) participants did not have any knowledge about the Informed Consent Form, 24 (30.8%) did not sign the Form, 48 (61.5%) participants did not read the Form and 49 (62.8%) did not understand the Form.

Conclusion: From the results of this study, it can be inferred that the extent patients are being informed is still not on intended levels and is not satisfactory. Informed Consent is still a topic to emphasize, improve and put into practice more effectively.

Keywords: Informed consent, consent form, third-party consent

INTRODUCTION

The two words: "to inform" and "consent", mean "to explain an issue or a notion in all details" and "approval" , respectively. They came to form the phrase "Informed Consent" for the first time in 1957 in the United States by attorney Paul G. Gebhard, during a medical malpractice trial (1). Subsequently, the right of a patient to make free decisions regarding his/her treatment after being informed has been recognized with the 3rd article in the Declaration of Lisbon, the first international text including the patient's rights which was adopted by World Medical Association in 1981, Lisbon. In the Declaration of Amsterdam, the necessity of informing the patients about their diagnosis and treatment in respect to their sociocultural level has been stated and informed consent has been approved as a prerequisite to any medical intervention.

Any intervention the doctor performs is considered as illegal. For a legal validity, the doctor performing the medical intervention must be competent, the intervention must be compatible with the literature and the patient must give consent for the intervention (2). The informed consent constitutes the legal validity of any medical intervention while providing the patient with information about the procedure and letting them participate either by admittance or denial. In this regard, with the Patients' Rights article 15 under the headline of Content of Informing, the Ministry of Health advises to explain the probable causes of the disease and its course, give details about the intervention, discussing other diagnostic options and treatment possibilities along with their pros and cons, explain possible complications and what could happen in case the patient refuses the treatment, inform the patient about the medications, recommend lifestyle changes and telling

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them how can get medical assistance in times of need. Information is given to the patient in a way they can understand, while taking their psychology into consideration and without resorting to medical terms, even an interpreter should sometimes be considered. If the patient is underage or if the patient lacks legal capacity, their legal representatives would be given information the same way. However, in a case of emergency, if the patient is not in condition to decide for themselves and there are no legal representatives present, an intervention can be performed so long there is no document stating the patient has rejected this intervention in the past (3).

This study aims to determine the extent the Informed Consent is being applied to patients both as a legal obligation as well as a sign of decent medical profession by conducting a questionnaire to inpatients of Trakya University Hospital.

MATERIAL AND METHODS

This is a descriptive cross-sectional survey study carried out between 18-25 May 2016 with 78 volunteers who are inpatients in surgical and inner medicine departments of Trakya University Hospital. The data collection form has been prepared with respect to Ministry of Health Patient's Rights Regulations to assess how the patients are being informed. It consists of 18 statements and 4 questions (age, gender, educational status, place of residence) towards the patient's demographic profile. The form has been applied in a face to face manner. Dichotomous variables (yes/no) have been used to assess the 18 statements and any answer other than "yes" has been considered as a "no", since as part of ethics, patients must be informed thoroughly.

Numbers and percentages have been used as descriptive statistics to assess the results. As for the assessment of the demographic data, arithmetic mean ± standard deviation (minimum-maximum) have been used. Since the form would be applied during the course of research, the required permission has been obtained from Trakya University Hospital Chief Physician.

RESULTS

In this study, the number of participants was 78 and the mean age was 59±17.47 (20-94). Out of all patients 41 (52.6%) of them were female, while 37 (47.4%) were male. Two (2.6%) participants lived in country side, 26 (33.3%) lived in county and 50 (64.1%) lived in city center. Five (6.4%) participants were never educated, 56 (71.8%) were primary and middle school graduates, 12 (15.4%) were high school graduates and 5 (6.4%) of them had bachelor's or associate degree (Table 1).

Table 1: Demographic characteristics of the participants (n=78)

	Number	*Percentage (%)*
Gender		
Male	41	52.6
Female	37	47.4
Place of Residence		
Country side	2	2.6
County	26	33.3
City center	50	64.1
Educational Status		
Not educated	5	6.4
Primary school	54	69.2
Middle school	2	2.6
High school	12	15.4
Associate degree	2	2.6
Bachelor	3	3.8

It has been confirmed that 47 (60.3 %) participants did not have any knowledge about the Informed Consent Form, while 24 (30.8%) did not sign the form, thus 48 (61.5%) participants did not read the Form and 49 (62.8%) did not understand the form.

It is declared by 57 (73.1%) patients that they have been informed about the possible causes of their disease, while 47 (60.3%) stated that they have been informed about the course of their disease, thus 53 (67.9%) declared that they have been told by whom the intervention would be done. On the other hand, 29 (32.7%) participants reported that they have not been informed where, how and in what way their medical intervention would be performed and how long it would take, 46 (59%) were not informed about other diagnostic and treatment options, thus 44 (56.4%) were not informed about the benefits and risks of other diagnostic and treatment options and their effect on their health. While 43 (55.1%) participants were informed about the possible benefits and risks of rejecting the treatment, 38 (35.9%) were informed about the complications which may occur during treatment and 42 (53.8%) were informed about the important properties of the medications they would use in the treatment. Forty-one (52.6%) participants reported that they were told how can they seek medical help and 48 (61.5%) reported that they were advised with critical lifestyle suggestions.

Out of all 54 (69.2%) participants thought that the doctor has informed them thoroughly, while 60

(76.9%) participants declared that they have asked anything they are troubled with and 57 (73.1%) stated that the doctor has answered everything they asked in a simple and understandable manner.

DISCUSSION

Obtaining an informed consent before any kind of medical intervention is a necessity both as a legal regulation and as professional ethics. The legal validity of a medical intervention is discussed under these main topics: the intervention should be done by an authorized person, informed consent must be obtained from the patient, the intervention must be compatible with the necessities of medicine (4). Unless these conditions have been met, any involvement of the doctor is illegal. Only in emergency situations, if the patient is not able to express himself / herself, if a legal representative is not present and if abstaining from any treatment would cause unavoidable results, then the intervention could be legally and ethically covered (5).

The doctor must see his/her patient face to face and inform the patient thoroughly according to their sociocultural level and must take their consent for any further process. However, usually the doctors perceive the Informed Consent as brief information and most of the times they think transmitting the Informed Consent Form via another health personnel or a computer is enough (6, 7). Out of the patients taking part in our study, 29.5% of them were thinking that their doctor have not informed them thoroughly. Again, 60.3% did not have knowledge about the Informed Consent and 62.8% stated that they did not understand the Form, while 66.7% declared they have signed a form they did not understand and they did not know much about.

The results of our study remain consistent with the literature. In the study of Özlü et al. (8), it has been confirmed that 55.5% of patient's consents are being taken by nurses, 54.5% of patients are being informed about the consent, additionally the study revealed that patients in fact do not understand the consent form they read and they sign it because they think it is formality. Similarly, in the study carried out by Ertem et al. (9) 60.9% of patients state that they understand what they are being told and 92.4% have accepted the form as a whole. On another aspect, forms consisting of less than 1000 words are being suggested. Furthermore, Erthem-Vehid et al. (10) reported that the mean value of word count in consent forms is approximately 1500.

While the patient is being informed and his/her consent is being obtained, every aspect must be fulfilled flawlessly. Judith et al. (11) conclude that the fact 70.2% patients answer with "a little bit" mean they have not been informed properly, just as we do from the results of our study.

In our study, it is clear that the extent patients are being informed is still not on intended levels and is not satisfactory. The fact that our study along with other existing studies have similar results reveals that Informed Consent is still a topic to emphasize, improve and put into practice more effectively.

Ethics Committee Approval: This study was approved by Scientific Researches Ethics Committee of Trakya University Medical Faculty.
Informed Consent: Written informed consent was obtained from the participants of this study.
Conflict of Interest: The authors declared no conflict of interest.
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