

## Original Article

# Assessing informed consent in medical malpractice cases associated with different surgical fields referring to Tehran's Commission of Forensic Medicine, 2017

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## Abstract

**Background:** Increasing the number of complaints against medical staff emphasizes the need for physicians to be more familiar with legal issues before and during providing medical services to the patient. Signing the informed consent form before medical practices and informing the patient of all possible outcomes can cause mental health and better collaboration of patients as well as increase the physician's self-confidence to provide better services. The current study aimed at determining the status of standard informed consent in medical cases related to different surgical fields referring to Tehran's Commission of Forensic Medicine during the first quarter of 2017.

**Materials and Methods:** In the current descriptive, cross-sectional study, the cases of medical malpractice related to different surgical fields referring to Tehran's Commission of Forensic Medicine in the first quarter of 2017 were investigated. Data were analyzed with SPSS version 16.

**Results:** In the current study, 124 cases of complaints against the medical staff of the surgical fields were examined. Based on the obtained data, the age and specialty of physicians, faculty status, and type of treatment center were effective in obtaining standard informed consent, and the highest percentage of allegations against the charge was related to cases attempted to obtain informed consent.

**Conclusion:** Obtaining the standard consent can significantly improve the patient-physician relationships and reduce the rate of medical malpractice complaints.

**Keywords:** Consent, Acquittance Letters, Medical Malpractice, Surgical Fields, Forensic Medicine

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## Introduction

Today, medical sciences gained tremendous achievements, as it can be said in the past 30 years it has developed more than thirty centuries. However, no person or system is free of error. Despite the best efforts of doctors and medical staff, the risk of

mistakes and error are always available<sup>1</sup>. International reports about the frequency of complaints against doctors in different countries indicate that unfortunately, in addition to significant scientific advances and the emergence of new technologies in diagnostic and therapeutic measures, the rate of complaints has risen, even if there was no error or the

doctor was innocent<sup>2</sup>.

Increasing the number of complaints is a global phenomenon that varies greatly between countries<sup>3</sup>. The rate of complaints against doctors in the United States increased from 3%-4% in 1970 to 8% in 1980, 20% in 1986, and 27% in 1990<sup>4</sup>. In Iran, the amount such complaints raised from 186 cases in 1995 to 2990 in 2009, and more than 10,000 in 2016.

This, although on the one hand, stems from the failure of physicians to establish relationships with their patient, on the other hand, there are several factors such as the press, television, and other social media, insurance companies, increasing the number of graduates in medical sciences in families, and attempting inappropriate actions to make more money in some physicians can affect the increasing rate of complaints. Increasing the number of complaints against the medical staff, emphasize the need for doctors to be more familiar with legal issues, and considering such regulations before and during the provision of healthcare services to the patient.

Signing the standard informed consent form (also referred to in the acquittance letter in-laws) before any diagnostic and therapeutic measure, and in other words, informing the patient of all aspects of the treatment process, including the type of medical or surgical services, as well as the possible outcomes of measures, in addition to creating mental relaxation and better collaboration of patient, it can increase the self-confidence of the physician in providing better healthcare services. The Iranian laws, using religious and juridical status, have a special focus on the issue of informed consent in medical practices<sup>5</sup>.

There are three types of consent, implied consent, explicit consent, and consent in specific cases. The implied consent is given verbally. Reference to a physician for medical purposes is an example of implied consent<sup>6</sup>. In explicit consent, the physician explains the patient the therapeutic method as well as its possible side, before the treatment, explicitly and clearly obtains consent from the patient, which may be orally or written. In special cases, for example, if the patient was not competent, the parents, his/her guardians, or their representatives should provide the consent, but in case of emergency, consent is not required<sup>7</sup>.

To the authors' best knowledge, this is the first study to examine the role of informed consent on the number of complaints and its possible impact on the final vote of the commission.

## Methods

The present descriptive, cross-sectional study was conducted on the complaints against medical malpractice related to different surgical fields referring to Tehran's Commission of Forensic Medicine in the first quarter of 2017. This article was extracted from an assistant thesis dissertation (number 77) with the ethical code of IR.SBMU.MSP.REC.1395.176 approved by the Ethics Committee of School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran. The statistical population of the study was all records complaints against doctors referred during the first quarter of 2017 to Tehran's Commission of Forensic Medicine.

The standard informed consent was developed by three medical schools of Shahid Beheshti, Tehran, and Iran, and sent to the state and private hospitals for exploitation. This form was designed by professors and experts from the Department of Forensic Medicine, Medical Ethics, and patient safety as well as the Deputy Administration of the universities<sup>8</sup>.

For this purpose, all the cases referred to the Tehran's Commission of Forensic Medicine relate to different surgical procedures (obstetrics and gynecology, *general* surgery, plastic surgery, neurosurgery, ENT, and related fellowships) in the first quarter of 2017 were evaluated, and data about the informed consent in terms of gender, age, expertise, faculty status, physician's experience, type of hospital, and commission final vote were collected and recorded in a researcher-made questionnaire. Data were then analyzed with SPSS version 16 using the Fisher exact and Chi-square tests.

## Results

In the current study, 124 cases of complaints in different surgical fields referring to Tehran's Commission of Forensic Medicine were enrolled, of which 26 (21%) cases had no informed consent and 98 (79%) cases had. Table 1 compares the status of informed consent based on physicians' characteristics.

**Table 1:** Comparison of informed consent obtaining in terms of variables among the studied cases.

Variable	Index	Without Informed Consent	With Informed Consent	Total	P-Value
Physician gender	Male	23 (21.3)	85(87.7)	108(100)	0.683
	Female	3 (18.7)	13 (81.3)	16(100)	
Physician age (yrs.)	31-40	7(46.15)	9(85.53)	16(100)	0.04
	41-50	7 (20)	39 (80)	46 (100)	
	51-60	6 (15.38)	27 (84.62)	33 (100)	
	Over 60	6 (6.25)	23 (93.75)	29 (100)	
Physician education	General practitioner	19 (70.37)	8 (29.63)	27 (100)	0.000
	Specialist	7 (7.45)	87 (92.55)	94 (100)	
	Sub-specialist	0 (0)	3 (100)	3 (100)	
Faculty status	No	25 (30.12)	58(69.88)	83 (100)	0.000
	Yes	1(2.43)	40 (97.57)	41 (100)	
Physician experience (yrs.)	Less than 10	0 (0)	3 (100)	3(100)	0.215
	11-20	4 (66.67)	2 (33.33)	6 (100)	
	21-30	2 (50)	2 (50)	4 (100)	
	over 30	0 (0)	1 (100)	1 (100)	
	Unknown	20 (18.18)	90 (81.82)	110 (100)	
Specialty	General practitioner	10 (71.42)	4 (28.58)	14 (100)	0.000
	Dentist	9 (69.23)	4 (30.77)	13 (100)	
	General surgery	6 (13.95)	37 (86.05)	43 (100)	
	Mouth and jaw surgery	0 (0)	3 (100)	3 (100)	
	Cardiac surgery	0 (0)	9 (100)	9 (100)	
	Neurosurgery	1 (4.28)	22 (95.62)	23 (100)	
	Plastic and cosmetic surgery	0 (0)	13 (100)	13 (100)	
	Pediatric surgery	0 (0)	2 (100)	2 (100)	
	Gastrointestinal surgery	0 (0)	1 (100)	1 (100)	
	Laparoscopic surgery	0 (0)	3 (100)	3 (100)	
Type of hospital	Private	17 (23.61)	55(76.39)	72 (100)	0.000
	Public	1 (10)	9 (90)	10 (100)	
	Public-teaching	0 (0)	31 (100)	31 (100)	
	Charity	0 (0)	1 (100)	1 (100)	
	Private office	8 (80)	2 (20)	10 (100)	
Final vote of the commission (percent)	Quittance	5 (7.47)	62 (92.53)	67 (100)	0.000
	Less than 10	14 (38.89)	22 (61.11)	36 (100)	
	11-20	0 (0)	7 (100)	7 (100)	
	21-30	7 (58.33)	5 (41.67)	12 (100)	
	31-40	0 (0)	1 (100)	1 (100)	
	50-100	0 (0)	1 (100)	1 (100)	

The findings of the current study showed that 108 male doctors (78.7%) and 16 female doctors (81.3%) got informed consent ( $P>0.05$ ). Evaluation of obtaining the informed consent based on the physicians' age showed that the age range above 60 years requested the highest number of consents, while it was in the lowest number by physicians within the age range 31-40 years ( $P<0.05$ ).

The findings of the study showed that all the specialties ( $n=3$ ) got informed consent. On the other hand, the majority of *general* practitioners lacked informed consent ( $P<0.001$ ). Evaluation of obtaining informed consent based on the faculty status, the findings showed that almost all faculty members

obtained informed consent ( $P<0.001$ ). To evaluate the status of informed consent based on the physicians' experiences, the findings showed that doctors with above 30 years and less than 10 years of experiences had the highest rate of obtaining informed consent (100%). The least of these were the doctors with more than 11-20 years of experiences. Evaluation of obtaining informed consent based on the type of specialty showed that all physicians in mouth and jaw, cardiac, plastic and cosmetic, pediatric, gastrointestinal, and laparoscopic surgeries attempted to obtain informed consent. Although most complaints were related to the *general* surgery cases, 86.5% of the *general* surgeons were also obtained the informed

consent. The *general* surgery cases constituted *general* practitioners and dentists (who attempted minor surgeries for their patients) mostly did not obtain informed consent ( $P < 0.001$ ).

Evaluation of obtaining informed consent based on the type of hospital, to the authors' best knowledge, the informed consent obtaining system is active in all public-teaching hospitals and all cases have a standard informed consent. A similar procedure is also observed in public non-teaching and private hospitals with 90% and 76.39% majority, respectively ( $P < 0.001$ ).

Evaluation of obtaining the informed consent based on the commission's final vote, the findings showed that half of the cases with informed consent were acquitted and about 29% were sentenced to pay fines less than 10% of diya (blood money) ( $P < 0.001$ ).

## Discussion

Today, specialization of medical affairs alongside financial and social problems has declined traditional physician-patient relationships. Although population growth, increasing the number of physicians, increasing the number of insured persons, and increasing the awareness of individuals of their rights are among the causes of the upward trend of complaints against doctors in recent years, the failure of physicians to communicate with patients is the main factor behind such claims. Given the fact that the patient forms the basis of complex medical services, the occurrence of errors in medical care practices is inevitable. In spite of the best efforts of doctors and medical personnel, the risk of such errors and mistakes always exist<sup>9</sup>.

"Satisfaction and complaint" like a double-edged sword, always threatens medical staff. Over the last decade, many studies were conducted using different methods on patient satisfaction, with similar results, and it is clear that about 70%-90% of people are satisfied with diagnostic and therapeutic services are currently provided. Klein et al. showed that for every written complaint there are 100 oral ones, and for every oral complaint there are four dissatisfied patients; therefore, for every written complaint there are 400 dissatisfied patients<sup>10</sup>.

The results of the inferential analysis showed that the age and degree of the physician are influential in

obtaining informed consent; so that physicians aged 41-50 years got the most informed consent. The degree of a physician was also contributed to the number of informed consents. As much as *general* practitioners did not pay enough attention to obtaining informed consent from their patients, the contrary, the majority of the specialists got informed consent. In the current study, the staffing of public-teaching hospitals, particularly faculty members as well as the clinicians dealing with high-risk situations were more interested in obtaining informed consent. Findings showed that obtaining informed consent could affect the final vote of the commission; therefore, the physicians who received the most informed consent were not sentenced.

Studies showed that one out of every 25 hospitalized patients may be damaged by medical malpractices, and 48,000 to 98,000 hospitalized patients die annually due to such errors. Improving human knowledge about diseases, along with the tragic patient-physician relationship (which often leads to a 100% medical guarantee to the patient), as well as awareness of individuals about their rights, resulted in the growing trend of complaints against doctors. Medical errors followed by complaints of patients, and finally, compensation seeking from them faced the medical community to a growing crisis to such an extent that its adverse effects are obvious in lack of risk-taking practices by physicians<sup>11</sup>.

In the UK, the doctor has to obtain informed consent, and the patients over 18 are competent to decide on their medical affairs. The patient should find a way to ask a question in order to better understand the illness and its treatment, and finally decide independently and consciously about admission or rejection of treatment interventions<sup>12</sup>. Actually patient satisfaction is not just getting a signature under a pre-typed form<sup>13</sup>. Age, literacy, and mental status of the patient are considered as important indicators in obtaining informed consent<sup>14</sup>.

With a close, careful, scientific look, it is clear that there are significant differences in some features of surgeries with repeated medical malpractices and the ones with lower rates of such errors. For example, the rate of error in sub-specialties surgeries is much less than that of *general* surgeries<sup>15</sup>.

Growth in the population, increased visits, and

increased *general* information on medicine as well as lack of adherence to the medical ethics, such as the stimulation of the patient by other medical staff, can justify part of the increase in complaints against medical practitioners, but this increase should be investigated in different time points carefully to provide opportunity with medical community providing healthcare services easy without fear of complaints. Because the psychological impact of complaints against doctors involves the entire medical community and is not just limited to doctors<sup>16</sup>.

## Conclusion

By obtaining informed consent and providing the necessary scientific and logical explanations to patients and their relatives regarding the medically induced injuries, their complications, the effectiveness of taken therapeutic measures, as well as inevitable side effects of therapeutic interventions, the rate of complaints can be reduced considerably. Therefore, it is suggested that by restoring medical ethics in medical education and holding workshops in order to educate the proper physician-patient relationship, and insistence of surgeons to obtain written informed consent can minimize the probability of complaints against doctors.

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