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Informed Consent in Tertiary Care Hospitals of Pakistan The Moral Magic of Consent

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Abstract

Objective: Consent is a fundamental component of a strong doctor-patient relationship. Informed consent (IC) enhances patient and doctor safety, fosters trust, and protects against litigation. This study aimed to assess whether standard international guidelines obtain informed consent and to identify potential contributing factors.

Methods: Questionnaire descriptive cross-sectional study was conducted at public sector hospitals of Karachi (October 2021-Aug. 2022) after ethical approval. A 12-point questionnaire was developed based on three categories, first to assess awareness & significance of IC, second regarding elements of IC & third for administrative part of IC. Indoor adult patients ≥18 years of age, who have undergone any surgical or medical procedures were ***included***. The critically ill, unconscious and those unable to give consent were ***excluded***. Data was analyzed by SPSS version 23.

Results: A total of 587 subjects were included, with a mean age of 43. There were 340(57.9%) males & 247(42.1%) females. 51.7% of respondents had an education level of <10 years. 51.1% & 48.9 % of subjects underwent medical related & surgical related procedures respectively. 426(72.6%) patients were aware of IC and 318(54.2%) responded affirmative to significance of IC. 407(69.3%) subjects were informed about treatment options prior to procedure, 349(59.5%) were informed about complications, while risks & benefits of procedure were discussed with 294(50.1%). 281(47.9%) of the patients were satisfied with the information about the procedure, and 288(49.1%) subjects understood the information. Of the respondents, 356(60.6%) stated that the language used wasn't appropriate for comprehension, 200(34.1%) identified language as a barrier, 185(31.5%) pointed to cultural factors, and 202(34.4%) believed that both language and culture were barriers to IC. 368(62.7%) of the subjects signed the IC, while the IC was signed by a family member in 219(37.3%). Only a minority of patients, 199(33.9%), felt that the consent process was free and fair, while 388(66.1%) believed their decision was influenced. Among them, 233(39.7%) felt influenced by the doctor, and 155(26.4%) attributed the influence to a family member.

Conclusion: There is significant room for improvement in achieving legally and ethically valid informed consent (IC). Literacy, language barriers, and cultural beliefs are major factors influencing patient's understanding of IC. Higher levels of education were associated with better comprehension of IC. The majority of patients reported that the consent process was neither free nor fair, with language and cultural barriers being significant obstacles. Enhancing the communication skills of healthcare professionals and incorporating formal training on obtaining IC at all levels, from undergraduate education to consultant training, is suggested.

Keywords: Informed Consent. Ethics. Shared decision making

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Introduction

Consent is an important tool in improving the ethical relationship between the patient and the physician. Informed consent has been labelled with different names like a shield or umbrella which serve to protect the patients from unnecessary interventions and also help keep patients shape their lives as they desire. In this way, informed consent also serves to protect Healthcare Professionals (HCPs) from any litigation.

Hippocratic writings (4-5 B.C.), Percival's medical ethics (1803), First code of ethics (18461847) of the American Medical Association (AMA), as well as historically significant

didactic writings on medical ethics in the eighteenth and nineteenth centuries all present a disappointing history from the perspective of IC. Thomas Percival's Historic Medical Ethics (1803) struggled with the issue of truth-telling.

The Nuremberg Code, in its first point mentions that for any human subject, it is extremely essential that voluntary consent should be obtained before any procedure and surgery Nuremberg Code (1947), the Declaration of Helsinki (1964), and the Belmont Report (1979) all these reports/codes gave specific importance to autonomy and informed consent. Evidence exists in records that the consent obtained does not appear to have been meaningful by contemporary standards of informed consent because most of the patient's rights have been ignored. It was common in the past for research to be conducted on slaves and servants without consent. In the 1950s and 1960s, there occurred little change regarding the disclosure of necessary information in obtaining consent. This development required a new term, and so informed was tacked onto consent which created the term of informed consent.[1]

Informed consent is nothing but authorisation by ourselves for any intervention according to his/her own will and permission.[2] Informed consent is the process by which a fully informed patient can opt for his/her choices about health care decisions. It is the ethical duty of the physician to involve the patient in health care decisions. Moreover, it is the legal and ethical right of the patient to be involved in treatment plan decisions. In the Western world, informed consent is fully developed, encompassing all aspects of valid consent. However, in developing countries, informed consent is often not obtained by its intended standards. To address this, we conducted a questionnaire-based study to assess whether informed consent is being practised according to established guidelines

Materials And Methods

After ethical approval, this descriptive cross-sectional study was conducted in public sector hospitals of Karachi (Civil Hospital Karachi & Dow University Hospital Ojha Campus Karachi). The study duration was from 1st October 2021 to 31st August 2022. A proforma pertinent to IC based on a 12-point questionnaire was developed in English and Urdu. Questions were based on three categories, the first category was to assess the awareness & significance of IC, the second category was to determine the elements of IC & third was for administrative parts of IC. The questions can be seen in Table 2.

The indoor adult patients ≥18 years of age, who have undergone any surgical or medical procedures were ***included***. The critically ill, unconscious patients and those who were unable to give consent were ***excluded***. Patients were then asked questions from the questionnaire, and responses were recorded as yes or no. Patients were guided if they required any further explanation of the questions. Responses were entered and analyzed by SPSS version 23. Data is presented as tables and bar graphs. The chi-square test was applied to study the association of various categories of questionnaires with educational status and gender. P-value <0.05 is taken as significant.

Results

A total of 587 subjects aged from 19 to 74 years with a mean age of 43 years participated in the study. 340(57.9%) were males & 247(42.1%) were females. Demographic data showed that most respondents had an education level of <10 years. Regarding procedure types, 51.1 % of procedures were medical-related conditions (including pleural tap, ascitic tap, bone marrow biopsies, renal/ liver biopsies, etc.) & 48.9 % were surgical-related procedures (table 1).

Table 1: Gender, education levels, and types of procedures undergone by participants (n=587).

	Variable	n (%); n=587
Gender	Male	340(57.9%)
	Female	247(42.1)
Education (years)	Unable To Read or Write	86(14.7%)
	Up to 5 years (Primary)	84(14.3%)
	Up to 10 years (Secondary)	133(22.7%)
	>10 years (matric and above)	284(48.4%)
Procedure Type	Hernia, gall bladder & laparotomy, etc.	169(28.8)
	Ascitic tap	168(28.6)
	Pleural tap	132(22.5%)
	Orthopaedic surgery	118(20.1%)

Regarding the questions assessing the knowledge about IC and its importance; 426 (72.6%) patients said yes to a question of whether they were aware of IC; and 318(54.2%) responded affirmatively to a question on their knowledge about the significance of IC (table 2).

Regarding category two questions for the assessment of the elements of IC which comprises alternate treatment options, complications, risks & benefits of the procedure, language understanding, and satisfaction from information given at the time of the process of IC. In responses to questions related to elements of IC, 407 (69.3%) subjects answered yes when asked if the HCP discussed the treatment options before the procedure, 349 (59.5%) said that the doctor informed them about the potential complications of the procedure and 294 (50.1%) said the doctor did discuss the risk & benefits. To a set of questions assessing how patients feel about IC, only 281 (47.9%) of the patients said that they were satisfied with the information provided to them, while 288 (49.1%) said that they understood the details provided. The majority of patients 356 (60.6%) thought that the language used was not appropriate for comprehension considering their education level. 200 (34.1%) of patients identified language as a main barrier for IC, whereas 185 (31.5%) considered culture and 202(34.4%) thought both language and culture are the barriers for IC.

Regarding the administrative part of IC, which was assessing the signing of IC, barriers of IC, and influence on the consent. 368 (62.7%) of the subjects signed the informed consent themselves while 219 (37.3%) said that a family member signed the IC. Lesser number of patients 199(33.9%) felt that the consent was free and fair while 388 (66.1%) felt the decision was influenced. 233(39.7%) felt the decision was influenced by the doctor whereas 155 (26.4%) said family member (table 2).

Table 2: The responses to various components of the questionnaire addressing the awareness, elements of informed consent and administrative components (n=587)

Variable	Response	n(%)
Category 1: Importance and awareness of Informed consent		
Are you aware of informed consent?	Yes	426(72.6)
	No	161(27.4)
Do you know the significance of informed consent	Yes	318(54.2)
	No	269(45.8)
Category 2: Elements of informed consent.		
Did the doctor discuss with you treatment options before the procedure?	Yes	407(69.3)
	No	180(30.7)
Did your doctor discuss with you the complications of the procedure before consent?	Yes	349(59.5)
	No	238(40.5)
Did your doctor mention the risks & benefits of the procedure?	Yes	294(50.1)
	No	293(49.9)
Are you satisfied with the information given to you?	Yes	281(47.9)
	No	306(52.1)
Did you understand the information given to you?	Yes	288(49.1)
	No	299(50.9)
Was the language used appropriate according to your education capacity?	Yes	231(39.4)
	No	356(60.6)
Category 3: Administrative component		
What are the barriers to informed consent?	Language	200(34.1)
	Cultural	185(31.5)
	Both	202(34.4)
Who signed the consent?	Self	368(62.7)
	Family	219(37.3)
Did consent was free and fair or influenced by someone?	Free &fair	199(33.9)
	Influenced	388(66.1)
Who influenced consent?	Doctor	233(39.7)
	Family	155(26.4)
	None	199(33.9)

Table 3: Responses to awareness and significance of IC concerning level of education (n=587)

Question	Response	Total	Primary	Secondary	matric & above	unable to read or write
Are you aware of informed consent?	Yes	426	62 (14.5%)	93 (21.8%)	249 (58.4%)	22 (5.2%)
	No	161	22 (13.6%)	40 (24.8%)	35 (21.7%)	64 (39.7%)
Do you know the significance of informed consent	Yes	318	31 (9.7%)	85 (26.7%)	171 (53.7%)	31 (9.7%)
	No	269	53 (19.7%)	48 (17.8%)	113 (42%)	55 (20.4%)

Table 4: Responses to awareness and significance of informed consent (IC) concerning gender (n=587)

Question	Response	Total n=587	Male n=340	Female n=247
Are you aware of informed consent?	Yes	426	245(57.5%)	181(42.5%)
	No	161	95(59%)	66(41%)
Do you know the significance of informed consent	Yes	318	252(79.2%)	66(20.7%)
	No	269	88(32.7%	181(67.3%)

Discussion

It has been well established in the Western world that informed consent is mandatory for any procedure/surgery or participation of human subjects in research studies. Therefore, sharing medical information with patients is a basic moral responsibility of physicians. Informed consent has a central role in clinical and research ethics. Patients have the full right to make decisions about their medical conditions and have the right to be given all available information relevant to such decisions. To obtain consent is not a discrete event; rather, it is a process that should be applied in all aspects of the physician-patient relationship.

The majority of the patients (72.6%) were aware of IC but nearly half of the patients (45.8%) didn't know the significance of IC. It alerts us that there is a lot of need to educate the public. When we analyzed the significance of informed consent with the education of the patient with cross-tabulation & chi-square test the results showed that the higher the education better understanding of the significance of IC & it was statistically significant (P value 0.001) Majority of the patients (60.6%) were not satisfied with the language which was used to explain IC according to education level & more than half (52.1%) were not satisfied about the adequacy of information and half of the patient (50.9%) didn't understand the information. In a regional study by Amir et al, 40.5% of patients understood the information which tells us the majority of the subjects were not fully informed. These findings alert us that much is needed to educate the HCP on using communication skills according to the education level of the patients. There are some studies; reviews and meta-analyses that have proved that obtaining informed consent is the basic building block for a successful doctor-patient relationship, and good communication has a positive impact on the emotional, physical and palliative health of the patient. Provision of the information about the condition produces a good effect on health and significantly reduces negative feelings, distress and pain. It greatly increases patient satisfaction and compliance with the treatment. Moreover, it is also mandatory for HCPs to consider the education level, intelligence & beliefs of individuals while communicating the patients.

The majority of the subjects (69.3%) discussed the complications of the procedure but nearly half (49.9%) of the subjects did not discuss the risks & benefits of the procedure. In a study by Amir et al, (48%) were informed about complications which means 52% were not informed about complications of the procedure[8] & these findings were also reported by another study by Jahan F et al in which 51.1 & 56.9% of subjects & relatives were not informed for the complications respectively. In another study conducted by Chima et al, in South Africa, 89.3% of HCPs provided benefits of the procedure, 81% were informed about treatment options & 95% of HCPs discussed the risks of the procedures to subjects. These findings are warning us that there is still a need for improvements in such regards.

Pakistan is a multi-linguistic country, & multicultural country; though Urdu is the national language still a lot of the population doesn't know the national language. Almost more than 70 languages are spoken in Pakistan as the first language. Language & culture play a great role in the IC. In this study, major barriers related to IC were language, and cultural & both (34.1%), (31.5%) & (34.4%) respectively. In a regional study by Khan RI, 87.5% of HCPs said language was the major barrier to IC. Responses

related to signing of the consent; 368 (62.7%) said self & 219(37.3%) said family. Our results showed improvements in self-signing of consent as compared to 29% & 52% as reported by previous literature. Compared to Western societies, our society is culturally different, with variations in education levels, financial status, and social norms. Therefore, it is essential to address not only language barriers but also cultural factors, as these are significant obstacles to obtaining informed consent.

Whether the IC was free and fair or influenced by someone? The majority of the patients 388(66.1%) said that IC was influenced & (39.7%) said HCPs, (and 26.4%) said family influenced the IC. In a study by Amir et al: 56% of subjects said the informed consent was influenced by doctor[8] & in another study by Jahan F et al 32.9% stated that consent was influenced by family & friends.[12] For legally & ethically valid IC; it is necessary that IC must be free & fair & there shouldn't be any influence either from family or HCP. In ethics, informed consent is deeply rooted in the ethical principle of autonomy. It is the patient's right to make autonomous decisions without any coercion. It keeps away the physician from carrying out any unwanted and experimental intervention.

A physician who administers medical intervention without obtaining consent may be considered to have committed battery. Treating a patient based on inadequate informed consent is considered medical negligence. Valid consent can be evaluated by country rules which are described in the constitution of their country. A good example is the Canadian Health Care Act which defines the important elements of valid consent, and procedures to determine the capacity of the patient, if a patient is found incapacitated then there is a defined procedure that can give consent on behalf of the patient. It has been well recognized in the literature that it is the physician's commitment to obtain valid consent before starting any intervention.

The basic target of informed consent is to provide an opportunity for patients to actively participate in medical decisions. For adequate, ethically and legally complete informed consent needs detailed information about the procedure/intervention, benefits & risks of the procedure, alternatives of the intervention, understanding of the patient information and acceptance & authorization of the procedure. Informed consent is considered valid when it is given by an individual who actively participates in discussion, information is given in layman's language and completely understands the decision. This must be given voluntarily by a competent individual & free from coercion. There are two different senses of informed consent. In the first sense, informed consent can be analyzed on account of autonomy because it is the person's autonomous choice. In the second sense, informed consent should be measured by social rules. If social rules are applied in the consent process, then it becomes an agreement rather than informed consent. In this sense informed consent loses its meaningful status but serves as only legally effective consent without being necessarily autonomous.

To put it another way, informed consent comprises five key elements: disclosure, comprehension, voluntariness, competence, and consent. Disclosure includes reasonable and relevant information by the physician/researcher to the subjects which includes its nature, purpose, risks and benefits & available alternatives & understanding of information. For legally legitimate informed consent; there are three approaches which include reasonable physician standard, reasonable patient standard& subjective standard. Of these three approaches reasonable patient standard approach has patient patient-centred approach but the drawback of this approach is that subjects cannot interpret technical information. Subjective standard is also reasonable but it might confuse the subjects. Therefore, a legitimate informed consent must fulfil all the essential elements.

When obtaining consent, the patient's capacity must be assessed, and a competent patient has the right to refuse treatment, even if it is life-saving. Consent should be voluntary, meaning that subjects must be free to make their decision without, undue coercion inducement, or a lack of choice. To ensure valid consent, patients should be allowed to ask questions and express concerns. Clinicians must actively involve patients in the consent process.

Our study is unique in that there is limited local research on informed consent, making it an important contribution to the field. Proper informed consent is a cornerstone of ethical healthcare practice, ensuring that patients are fully aware of their treatment options and the associated risks and benefits. For clinicians, it enhances patient trust, encourages shared decision-making, and reduces the risk of legal disputes. For policymakers, establishing clear guidelines for obtaining informed consent helps standardize healthcare practices, ensuring patient autonomy is respected while maintaining accountability. Furthermore, a robust informed consent process improves healthcare outcomes by fostering patient involvement and satisfaction, making it essential for both effective clinical practice and sound healthcare policy.

Conclusion

The study highlighted a significant need for improvement in obtaining legally and ethically valid informed consent. Education, language, culture, and female gender were identified as major factors that influence understanding of IC. Higher levels of education were associated with a better understanding of informed consent. The majority of patients expressed that informed consent was neither free nor fair, with language and cultural barriers being major obstacles. Additionally, there is a need to enhance the communication skills of healthcare professionals (HCPs). .

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