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PERCEPTION AND PRACTICES OF OBTAINING CONSENT AMONG MEDICAL PROFESSIONALS

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ABSTRACT:

Objectives: Medical professional's knowledge of law governing medical practice is essential in securing the patients' rights. Given the spurt in medico legal compensation cases against the medical professionals in India, partly due to documentation of medical record pertaining to obtain Consent before treatment, we decided to perform an examining the levels of clinician's perception and awareness of Informed Consent (IC) among surgeons.

Material and Methods: A questionnaire-based cross sectional survey among surgeon both in the government and private hospital was conducted.

Results: A total 150 participants included in present study of which 66% were of males and 34% female. Majority of were from Private sector (58%) & around 64% had < 5 years' experience in medical field following post-graduation. Majority of participants had taken consent from both patients & relatives. About 87% participants always explained procedure details to patient/relative and procedure related complications were always explained by about fifty percent participants. About one third were agreed that they did not wait for relative to obtain consent when patient was conscious while 82% participants did not wait for relative to obtain consent when patient was unconscious. Regarding video consent, one forth was not agreed while about half were agreed that it should be optional or case based.

Conclusion: All clinicians & medical researchers should take Informed Consent seriously to dignify the patient-doctor relationship & to change their attitude and acknowledge the patient's autonomy. In the present study majority of the clinician were well aware of the consent procedure, however possibility of information bias did exist.

Key words: Informed Consent, tertiary hospital, video consent.

INTRODUCTION

Informed Consent (IC) is one of the important factors in the medical treatment. It is required to obtain the consent of the patient for any procedure. Patient has right to refuse for the treatment, even though the treatment is life saving. Hence, patient can accelerate his recovery by

participating in decision making **(1, 2)**. Consent form is a defence tool for hospital against claimants. Informed consent should have requirements, such as: presenting information to patient by attending physician, patient perception and authority, patient competency in decision making, consent form signing, and factors affecting on patient- physician interaction **(3, 4, 5).** Consent is fundamental and established principle in the Indian law. Every person has the right to determine what shall be done to his body. According to IPC sections 96 to 102, 104, 106, Self-defence of body provides right to the protection of bodily integrity against invasion by other.

Many studies strongly support a patient-centred approach in clinical practice, **(6, 7)** however, some cultures may not consider it ideal. Involvement of patients with respect & autonomy may mean allowing a person to delegate certain decisions, if that is his or her wish. Disclosing the diagnosis or prognosis to patients, especially when it relates to potentially fatal illnesses like cancer, is not the norm in many parts of the world. Global countries like In Eastern Europe, Italy, France, , most of Asia, America, and the Middle East, physicians and patients often feel that withholding medical information is more humane and ethical.**(8)** According to Navajo patients' and families' beliefs, direct information about risks from a procedure or a diagnosis is harmful and that talking about death can actually hasten its arrival.**(9)** With the revolution in information technology, the patients and their family members are much better informed about medical matters and want to actively participate in decision-making, and these realities must be considered in clinical practice. Medical doctors, out of respect for themselves and their patients, must obtain Informed Consent.

In India, studies on this issue are very few and to the best of our knowledge, none has been done in Rajasthan, India. We therefore aim to investigate the perceptions and practices among attending medical professionals in matters relating to Informed consent in selected hospitals in Rajasthan.

MATERIAL AND METHODS

This was a cross-sectional interview and hospital-based study. The study was conducted among the surgical fraternity in Rajasthan, both in government and private sector. A pre-formed, pre-tested questionnaire was distributed either by email or personally, which was collected after completion. A 14-item English version questionnaire was derived from other published studies dealing with the same topic as well as from our own experience. . The questions were framed around issues of medical paternalism, Informed Consent (IC), medical ethics and patient autonomy. Doctors were also asked how they make ethical judgments in the face of dilemmas. The questionnaire had a cover page explaining the importance of IC because of modern ethical issues and medico legal consequences.

A written format explaining the purpose of the research was prepared and signed by the participants before filling the questionnaire.

RESULTS

A total of 200 questionnaires were distributed and 150 were received with a response rate of 75% as shown in Table 1. The Kolmogrov-

Smirnov test revealed non normal distribution of the data. The gender distribution was 99 (66%) of males and rest of female & Majority of them were Associate professor / assistant professor (58%) followed by senior residents (32%) who participated in current study.

Regarding experience in medical field, around sixty percents (64.1%) had < 5 years whereas one fifth (20%) had 6 to 10 years experience. (Table-1)

Table 1: Demographic details of Participants

Gender	
Male	99(66%)
Female	51 (34)
Designation	
Private Sector	87(58%)
Government Sector	63 (42%)
Duration of experience (Years)	
≤ 5	96 (64%)
6-10	30 (20%)
11-15	12(8%)
> 15	12(8%)

According to Table 2, results showed that 90% of participants had taken consent from both patients & relatives of patients and majority (90%) were agreed that these consent has been taken by operating surgeon or assistant / resident doctors.

About 87% participants had explained always about procedure to patient / relative and procedure related complication had been discussed by operating surgeon or assistant / resident doctors not by staff nurse. These procedures related complication were always explained by 52% participant while 48% were discussed sometime.

Almost all participants were aware of difference between implied and informed consent. About nine tenth participants were ensured that consent was in language which was understandable to patients while three fourth were ensured that there was no undue influence. About one third agreed that they did not wait for relative to arrive for consent when patient was conscious.

Only one fourth (24%) had wait for relative for consent when patient was conscious. A condition like patient is unconscious & no one available, 82% participants did not wait for relative to arrive for consent. Only one sixth participants did wait for relative for consent at the time of procedure. A special situation like some non life threatening unrelated disease is found during procedure, about two third participants viewed that they intervened the new pathology during same setting after obtaining consent from relatives while about one fourth were intervened the new pathology during same setting without consent.

Opinion regarding video consent, one forth were not agreed for it while about half were agreed that it should be optional or case based. Most of consent has to be taken at bedside while only one tenth were taken at counselling room.

More than four fifth participants had not face any legal or social problem while only 11 % were obtained once such type of problem during carrier.

Table 2: Awareness of Informed consent

Items	N (%)
From whom the consent is taken	
Patient only	12(8%)
Relatives	3(2%)
Both	135(90%)
Who is responsible for obtaining the consent	
Operating surgeon	95(63.33)
Assistant/resident doctor	40(26.67)
Staff nurse	15(10%)
Are you explaining the patient/ Relative about procedure	
Always	131(87.3)
Sometimes	12(8)
Never	7(4.67)
Who explain the procedure / procedure related complication	
Operating surgeon	130(87.3)
Assistant/resident doctor	20(12.67)
Staff nurse	0(0)
Do you explain the complication in detail	
Always	78(52)
Sometimes	72(48)
Never	0(0)
Are you aware of the difference between implied and informed consent	
Yes	144(96)
No	6(4)
Sometimes	0(0)
Do you ensure that consent is in language which is understandable to patient	
Yes	136(90.6)
No	0(0)
Sometimes	14(9.33)
Do you ensure that there is no undue influence	
Yes	112(74.6)
No	18(12)
Sometimes	20(13.33)
Do you wait for relative for consent when no one available and patient is conscious	
Yes	36(24)

No	54(36)
Sometimes	60(40)
Do you wait for relative for consent when no one available and patient is unconscious	
Yes	24(16)
No	123(82)
Sometimes	3(2)
What you do during surgery if some non life threatening unrelated disease is found	
Leave the disease as such	18(12)
Intervene the new pathology during same setting after obtaining consent from relatives	96(64)
Intervene the new pathology during same setting Without consent	36(24)
In your opinion video consent should be	
Mandatory	40(26.67)
Optional/case based	72(48)
Not needed	38(25.33)
Where do you take consent	
Bedside	132(88)
Counselling room	15(10)
No specified area	3(2)
Have you ever faced legal / Social problem for not obtaining	
Never consent	123(82)
Once	17(11.33)
More than once	10(6.67)

DISCUSSION

General awareness on informed consent is a reasonable physician standard. It is of significance noting that medical paternalism occurs to some extent in most societies of India and other countries and also probably cannot be eliminated. **(10)** Medical practice is a moral practice and it requires doctors to make judgment on what is best for their patients. The limitations of this study include the potential for information bias. The respondent may be providing an anticipated response that is acceptable to the researcher, instead of reflecting the actual response in a real-life situation. Other possible reasons include a small sample size or an invalid assumption. Their authority is hardly ever challenged, and their advice, seldom questioned. They are supposed to reassure and comfort the patients, not to frighten them. Malpractice suits against physicians and hospitals hardly ever occur.

In our study, majority of participants take consent both patients & family members.

Consideration of family member is a necessity in our society because health expenditure is borne mostly by the family, due to limited resources, giving the family a central role in decision-making. The family is the fundamental unit of society, and people generally live in extended families with collective earnings, with interdependent members taking an interest in all matters pertaining to life and death. There are no third party payers, and a health insurance system is adopted by few. Most patients avoid the responsibility of decision-making and defer this role to the family or the doctor. Women, in particular, do not give consent unless they get approval from their husband or the head of the family. In some societies, women cannot make medical decisions for themselves; instead, that right is accorded to their husbands. **(11)** There is also no concept of nursing homes for the aged or for the terminally ill and debilitated patients in Rajasthan for in their homes, usually by the female members of the extended family.

In present study, majority of participant explained about the procedure & its complication to patients. The patient must be told what is to be done and why. It is essential to regard patient autonomy and his participation in health service so they could enhance their knowledge & complications about disease. **(12, 13)** Hence, patient can accelerate his recovery by participating in decision making. **(1, 2)** It is also a defence tool for hospital against claimants and it should have requirements, such as presenting information to patient by attending physician, patient perception and authority, patient competency in decision making, and factors affecting on patient- physician interaction. **(3, 4)** Patient treating without his informed consent probably can sues and consent with reluctance, fear or japery is not valid. So it is a kind of risk management and indicates responsible person. **(14)** In taking informed consent, clinician should pursue ethics and pay their respects to patient decisions about practice and his autonomy. Consent should be voluntary and patient should have a good perception of nature of proposed practice, because legally, any practice without consent is equal public rights violation. **(15)**

More than eighty percent participant did not agreed to wait for relatives if patient was unconscious and no one was available at that time, a clinician may perform emergency management based on the doctrine of necessity or implied consent to save lives.

In present study, more than four fifth participants take consent at bedside. Only 10% took consent in counselling room. This was important and serious issues of privacy and confidentiality of patients' right.

Only 12 % of the participant said to leave the non-life-threatening new pathology as such, for which prior consent has not been taken. 88% agreed to deal with new pathology after taking consent from relative or even without consent.

Supreme court of India has given its judgement in **Samira Kohli v. Dr. Prabha Manchanda (16), Supreme Court of India** has adequately answered the question. Supreme court held *We therefore hold that in Medical Law, where a surgeon is consulted by a patient, and consent of the patient is taken for diagnostic procedure / surgery, such consent cannot be considered as authorisation or permission to perform therapeutic surgery either conservative or radical (except in life threatening or emergent situations). Similarly where the consent by the patient is for a particular operative surgery, it*

cannot be treated as consent for an unauthorized additional procedure involving removal of an organ, only on the ground that such removal is beneficial to the patient.

Analysis of this study also revealed that 88% participant did not face any legal / social problem because most of patents might have trusted their doctor to do the right thing and did not mind what happened to them provided they were made better.

Written consent is essential before performing any medical examination and surgical procedures, which should be acquired from patient in the presence of impartial party. In the era of advance of awareness, headway of learning and technique, there is a development of a belief that the patient will be injudiciously treated, if the clinician is not having a proper knowledge and rational care. Appropriate consultation, clinical confidence, consent and authentic documentation will never place the medical doctor in Medical litigation. While it is not officially necessary but it is good medical practice to counsel with relatives of patient in patients good faith.

CONCLUSION:

As a result, it can be concluded that not only all clinicians but also medical researchers should take Informed Consent seriously to dignify the patient-doctor relationship and there should be no compromise in providing information that is not "reasonable" in the eyes of the court. In case of emergency, a doctor can start the treatment of a patient without the consent of the patient to save his life. In the present study majority of the clinician were well aware of the consent procedure, however possibility of information bias did exist.

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