

Knowledge and attitude regarding written consent in hospital practice among patients and family members

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ABSTRACT:Informed consent for clinical treatment has become a vital part of contemporary medical practice; it means different things in different contexts, is variably practiced and rarely achieves the theoretical ideal. The informed consent process requires the physician to explain in sufficient detail, the diagnostic, therapeutic and prognostic reasoning that leads to his expert decision on what is in the best interest of the patient. The practice of informed consent has historical roots in various disciplines and plays a critical role in hospital as we are entering the era of patient as a consumer and doctor as a service provider.¹The aim of the study is to assess the knowledge and attitude regarding written consent in hospital practice among patients and family members in selected health care institute.**MATERIALS AND METHODS:** Non-Experimental Descriptive design used on 100samples. Non-probability purposive sampling technique was used and was statically analysed. Ethical clearance was taken from the Institutional ethics committee. Data analysis was done using descriptive statistics. **RESULTS:**The study results showed that majority 61% of patients have average knowledge, 23% samples have good knowledge and 16% samples have poor knowledge with the mean of 9.36 and SD of 3.39. The majority of samples 66% in group of family members have average knowledge, 25% samples have good knowledge and 11% samples have poor knowledge with the mean of 9.95 and SD of 3.2. Majority 65% patients strongly agree that signing the consent form is a legal requirement. Majority 48% patients agree that patient have the right to change your mind after signing the consent form. Majority 57% patients agree that consent form help because me aware of risks of the procedure. Majority 54% patients agree that consent form gave the doctors control over what happened. Majority 44% patients agree that consent form explain that what was going to proceed. Majority 50% patients strongly agree that signing the consent form is to protect the hospital. Majority 48% patients strongly agree that Consent form explain the risk involved in having the procedure. **CONCLUSION:**The findings showed demographic variables like age and marital status of the patients are associated with the knowledge regarding written consent. This study will be vital part for the clinical setting. Written consent will helpful for legal as well as support patient defined goals. It will be helpful and provide efficient safeguard. It also is preventing unwanted procedures.

Keywords: Assess, Knowledge, Written Consent, Patients, Health Care Institute

INTRODUCTION

In India, there has been an increase in the number of malpractice suits that have arisen because of lack of informed consent or inadequate consent from the patients for various procedures. Informed consent is when a healthcare provider like a doctor, nurse, or other healthcare professional explains a medical treatment to a patient before the patient agrees to it. This type of communication lets the patient ask questions and accept or deny treatment. In a healthcare setting, the process of informed consent includes: your ability to make a decision, explanation of information needed to make the decision, your understanding of the medical information and your voluntary decision to get treatment.¹Informed consent has its roots in the 1947 Nuremberg Code and the 1964 Declaration of Helsinki and is now a guiding principle for conduct in medical research.^{2,3}Within its ethical and legal foundations.⁴Informed consent has two specific goals in clinical research: (i) to respect and promote a participant's autonomy; and (ii) to protect participants from harm.^{5,6} Obtaining written informed consent from participants before enrolment in a study is an internationally accepted standard.⁷ Five concepts must be considered in establishing informed consent: voluntariness, capacity, disclosure, understanding and decision.⁸Voluntariness means that an individual's decision to participate is made without coercion or persuasion. Capacity relates to an individual's ability to make decisions that stems from his or her ability to understand the information provided. Disclosure involves giving research participants all relevant information about the research, including its nature, purpose, risks and potential benefits as well as the alternatives available.⁹ Understanding implies that

research participants are able to comprehend the information provided and appreciate its relevance to their personal situations.¹⁰

NEED OF THE STUDY: Informed consent for clinical treatment has become a vital part of contemporary medical practice; it means different things in different contexts, is variably practiced and rarely achieves the theoretical ideal. It become the primary paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine. It may be used for different purposes in different contexts: legal, ethical or administrative. Western countries have enshrined these concepts of informed consent, privacy and confidentiality in federal or state laws and codes of ethics, such law-making is almost non-existent in Pakistan although there have been some recent efforts to create ethical guidelines for research and medical practice. The regulatory body of medical practitioners has formulated a code of ethics for all doctors, although no concrete steps have been taken to ensure their application.¹¹Most other work on this subject focuses on research ethics and is currently limited to individual institutions or some non-governmental organizations.¹²Public awareness of their rights to informed consent and privacy is often low. Previous qualitative research has shown that a significant number of physicians do not think it is necessary to obtain a proper consent after providing the patients with thorough information. In hospital duty researcher has observed that Patient and family members always has query about different forms in hospital regarding admission and any procedure. So researcher wants to do this study as he is aware that the right of the patients and relatives is very essential from legal aspect also and they have right to know the information about all document in the hospital.

AIM: To assess the knowledge and attitude of the patients and family member’s knowledge of written consent with demographic variables.

RESULT:Demographic characteristics of patients

According to age, majority 40% patients are from 31-45 years group. Majority patients 69% are unmarried, majorities 56% are male and 44% are female. Majority 46% are having education as higher secondary. Majority 44% are employed. Majority 64% not underwent any surgical procedure previously.

Demographic characteristics of family members

According to age, majority 50% family members are from 31-45 years group. Majority patients 73% are unmarried. Majorities 62% are male and 38% are female. According to education Majority 38% are having education as higher secondary. Majority 44% are employed. Majority of family member 25% are having relation with the patient as husband - wife.

Findings related to the level of knowledge regarding written consent in hospital practice among patients and family members.

Table no.1 -Level of knowledge regarding written consent in hospital practice among patients

N=100

Level of knowledge	Frequency	Percentage	Mean	SD
Poor knowledge	16	16	4.37	.88
Average knowledge	61	61	8.95	1.96
Good knowledge	23	23	13.91	.79
Mean	9.36			
SD	3.39			

The above table depicts that Majority of samples in group of patients have average knowledge i.e. 61%, 23% samples have good knowledge and 16% samples have poor knowledge.

N=100

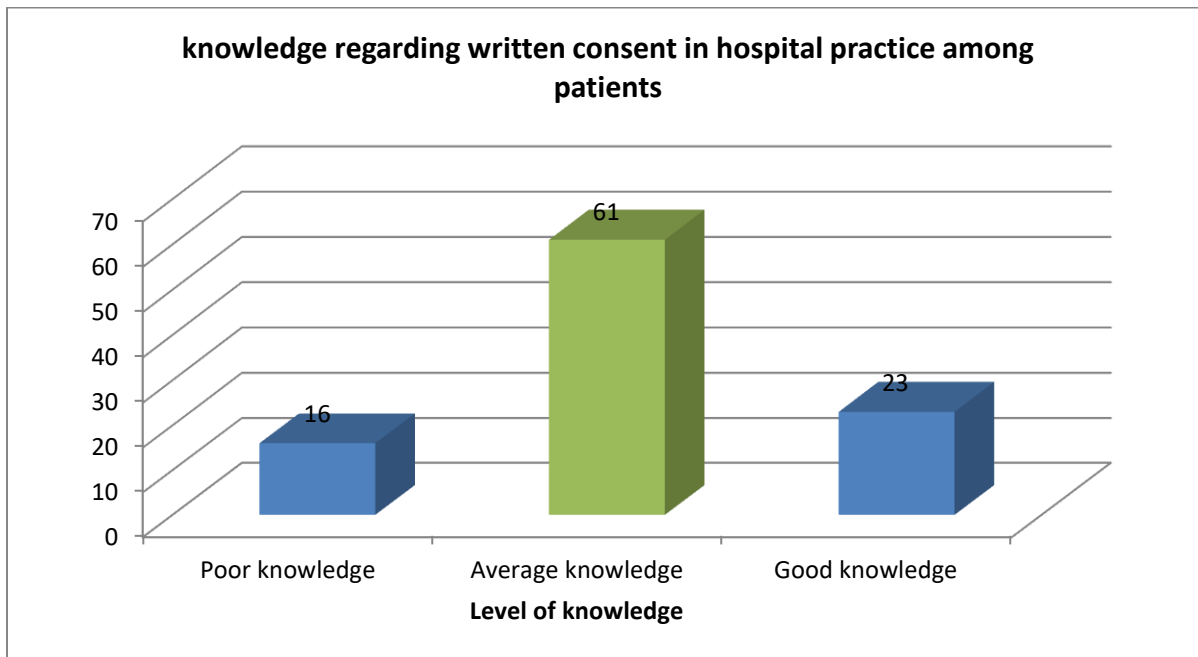


Figure no.1- Knowledge regarding written consent in hospital practice among patients

Table no.2- Level of knowledge regarding written consent in hospital practice among family members

N=100

Level of knowledge	Frequency	Percentage	Mean	SD
Poor knowledge	11	11	4.2	.786
Average knowledge	64	64	9.48	2.13
Good knowledge	25	25	13.64	.81
Mean	9.95			
SD	3.20			

The above table depicts that Majority of samples in group of family members have average knowledge i.e. 66%, 25% samples have good knowledge and 11% samples have poor knowledge.

Figure no.2- Knowledge regarding written consent in hospital practice among family members

N=100

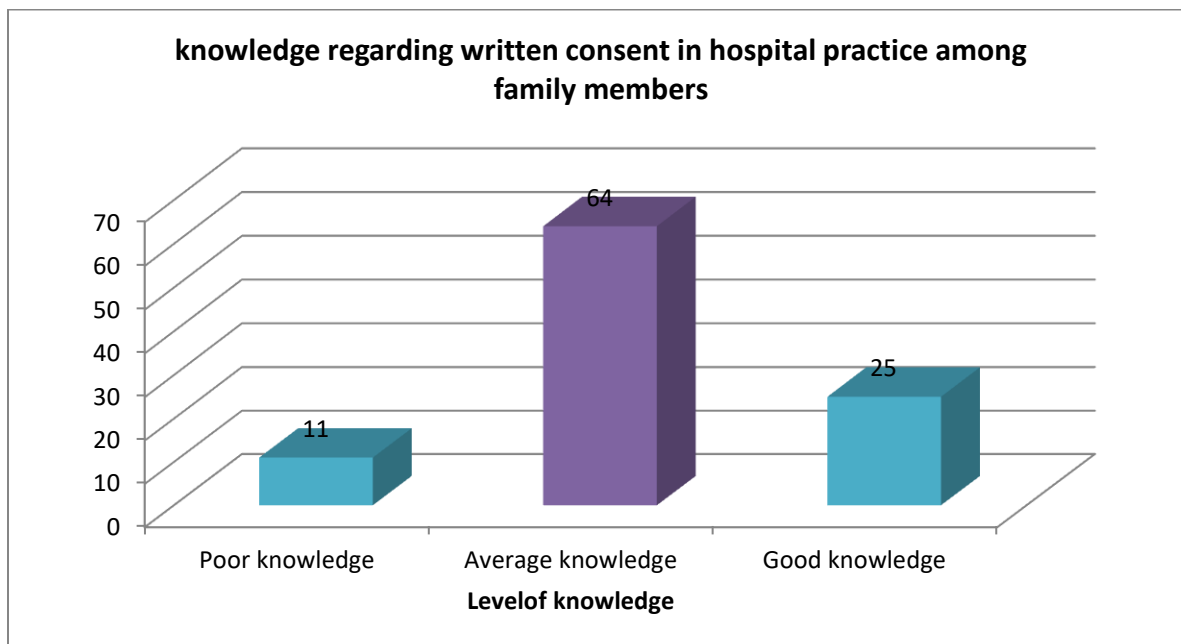


Figure no.2- Knowledge regarding written consent in hospital practice among family members

Findings related to the attitude regarding written consent in hospital practice among patients and family members.

The data presented description of attitude regarding written consent in hospital practice among patients. Majority 65% patients strongly agree that signing the consent form is a legal requirement. Majority 48% patients agree that patient have the right to change your mind after signing the consent form. Majority 57% patients agree that consent form help because me aware of risks of the procedure. Majority 54% patients agree that consent form gave the doctors control over what happened. Majority 44% patients agree that consent form explain that what was going to proceed. Majority 50% patients strongly agree that signing the consent form is to protect the hospital. Majority 48% patients strongly agree that Consent form explain the risk involved in having the procedure. Majority 44% patients agree that Counselling is done before signing the consent. Majority 53% patients strongly agree that before signing the consent form you should know rights of patients. Majority 43% patients strongly agree that Doctors provides informed (verbal) consent. Majority 50% patients strongly agree that Nurses provides written consent. Majority 50% patients agree that Patient's consent helps with the treatment. Majority 43% patients disagree that Informed consent is not required if the procedure is simple and common. Majority 44% patients agree that Informed consent is a right that belongs to patients.

DISCUSSION:The purpose of the present study is to assess the knowledge and attitude regarding written consent in hospital practice among patients and family members in selected health care institute of bangalore city. A similar study conducted by Yashashwini N Simha, et al in 2019 on assessing the legal nature of informed consent and attitude of patients attending outpatient departments of a dental hospital in Bengaluru City: A cross-sectional study. Out of 376 (100%) participants, majority (103 [27.4%]) belonged to the age group of 21–30 years. With regard to the scores, 163 (74.4%) males had a score range of 7–12 as compared to females (117 [74.4%]). Study concluded that Informed consent process is intended to protect patients and to promote an enlightened ethics in patient–dentist relationship. Our study showed that many patients had limited knowledge of the legal implications of signing or not signing consent forms and did not recognize written consent as primarily serving their interest.¹⁵

The another study was done on Knowledge and attitude regarding written consent in hospital practice among patients and family members by Ayesha Humayun, et al. 2008. Result indicate that Some degree of informed consent was obtained from only 9.7% patients in the public hospital and 47.8% in the private hospital. 81.4% of patients in the public hospital and 88.4% in the private hospital were accorded at least some degree of privacy. Complete informational confidentiality was maintained only in 10.8% and 35.5%

of cases in public & private hospitals respectively. Informed consent and confidentiality were better practiced in the private compared to the public hospital (two-sample t-test > 2 , p value < 0.05). There was marked disparity between the patients' perspective of these ethical practices and the assessment of our trained data collectors.¹⁴

CONCLUSION:

Study concludes that majority of samples in group of family members have average knowledge and some have good knowledge. Majority patients accept that signing the consent form is a legal requirement, patient have the right to change your mind after signing the consent form, consent form help because me aware of risks of the procedure. Authority wise distribution shows that consent form gave the doctors control over what happened, consent form explain that what was going to proceed, signing the consent form is to protect the hospital and consent form explain the risk involved in having the procedure. The findings showed demographic variables like age and marital status of the patients are associated with the knowledge regarding written consent.

In the medical setting consent is the legal part as well as benefit for saving the patient document. It is also useful for recording and reporting. It will protect health professional because if any medical error happens it will shows as legal document. This study will be vital part for the clinical setting. Written consent will helpful for legal as well as support patient defined goals. It will helpful and provide efficient safeguard. It also prevents unwanted procedures.

CONFLICT OF INTEREST

Researcher has no conflict during the research work. Also they have interested in hospital for doing research.

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There is no funding Source for this study.

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