

Original Research Article

Consent in medical practice – Perceptions of patients towards legal aspects of informed consent

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Abstract

Background: Informed consent is way of providing necessary information to the patients and helping them for decision making. All the pros and cons of procedure must be explained to the patients in the language he or she can understand. Just taking signature of patient on consent form without proper explanation and understanding of him is violating entire process of informed consent.

Materials and methods: A cross sectional, observational study was conducted over 121 patients aged 18 years and above who came to Gayatri Hospital, Gandhinagar after obtaining their informed written consent for participation in survey regarding informed consent. All participants were subjected to pretested and validated questionnaire (Likert type scale) regarding legal aspects of informed consent.

Results: Out of 121 participants, only 100 participants' responses were included for analysis. Among 100 participants 73 were male and 27 were female. 78% agreed that informed consent is must for any procedure. 61% agreed that signing consent form is just a formality. 91% believed that informed consent is protective shield for doctors. 88% believed that informed consent is legally necessary. Only 52% agree that consent form is meant to protect patients' rights. 77% felt that signing consent form

eliminate patients' right to compensation. 82% wanted to know everything but letting decision left on doctor.

Conclusion: The study concluded that there is a wide gap between actual concept of informed consent and perceptions of patients for the same. Patient awareness programs must be conducted by appropriate authority with help of media and television to improve their knowledge and preserve their rights.

Key words

Informed consent, Medical practice, Perceptions, Patients.

Introduction

Right to choose and know about procedure is fundamental thing of patients' autonomy. Informed consent is way of providing necessary information to the patients and helping them for decision making [1]. All the pros and cons of procedure must be explained to the patients in the language he or she can understand [2, 3]. Just taking signature of patient on consent form without proper explanation and understanding of him is violating entire process of informed consent [1, 2].

Even today, patients of poor socio-economical class are blindly signing consent form without any questions. Many people are not aware of what they must know and what to understand about particular procedure. In hope of guaranteed cure, they put themselves in hand of doctors without any thinking [3, 4]. The objective of this study was to assess perceptions of patients towards legal aspects of informed consent in medical practice. Additional objective of this study was to know whether patients really want to decide for themselves after proper explanation.

Material and methods

A cross sectional, observational study was conducted over 121 patients aged 18 years and above who came to Gayatri Hospital, Gandhinagar after obtaining their informed written consent for participation in survey regarding informed consent. All participants were subjected to pretested and validated [5-8] questionnaire (Likert type scale) regarding legal aspects of informed consent. Each question was varied in response from Disagree, Not sure and

Agree. Responses given by the participants were entered into MS excel sheet and analyzed via SPSS. Frequency and percentage of each response was tabulated and assessed.

Results

Out of 121 participants, only 100 participants' responses were included for analysis while rest 21 participants' responses were excluded because of incomplete and multiple answers given by them. Among 100 participants, 73 were male and 27 were female.

Perceptions of patients toward legal aspects of informed consent were as per Table – 1. 78% agreed that informed consent is must for any procedure. 61% agreed that signing consent form is just a formality. 91% believed that informed consent is protective shield for doctors. 88% believed that informed consent is legally necessary. Only 52% agree that consent form is meant to protect patients' rights. 77% felt that signing consent form eliminate patients' right to compensation. 81% showed that patient can refuse for procedure after signing consent. 68% believed that signed consent form proves that patient understood nature and consequences of procedure. 89% agreed that patients' relatives can sign consent form on behalf of patient. 79% felt that without sign in consent form, operation is illegal. (**Table – 1**)

Perceptions of patients towards willingness to know before signing consent form were as per **Table – 2**. 98% were willing to know cost of procedure. 78% were willing to know reason of procedure. 79% were willing to know time taken

by the procedure. 83% desired to know complications of procedure. 74% wanted to know precautions need to be taken before and after procedure. 81% wanted to know limitations of quality of life after procedure. 91% were willing to know success rate of procedure. 88% wanted to know duration of stay at hospital after procedure. 57% wanted to know alternative way of suggested procedure. Only 51% wanted to know steps of procedure. (Table – 2)

Table – 1: Perceptions of patients towards legal aspects of informed consent.

Sr. No.	Questions	Responses of participants (%)		
		Disagree	Not sure	Agree
1	Informed consent is must for any procedure	11	11	78
2	Signing consent form is just a formality	32	7	61
3	Informed consent is protective shield for doctors	7	2	91
4	Informed consent is legally necessary	9	3	88
5	Consent form is meant to protect patients' rights	15	33	52
6	Signing consent form eliminate patients' right to compensation	11	12	77
7	Patient can refuse for procedure after signing consent	2	17	81
8	Signed consent form proves that patient understood nature and consequences of procedure	20	12	68
9	Patients' relatives can sign consent form on behalf of patient	4	7	89
10	Without sign in consent form, operation is illegal	11	10	79

Table – 2: Perceptions of patients towards willingness to know before signing consent form.

Sr. No.	Questions (I want to know)	Responses of participants (%)		
		Disagree	Not sure	Agree
1	Cost of procedure	1	1	98
2	Reason of procedure	14	8	78
3	Time taken by the procedure	8	13	79
4	Complications of procedure	6	11	83
5	Precautions need to be taken before and after procedure	6	20	74
6	Limitations of quality of life after procedure	9	10	81
7	Success rate of procedure	4	5	91
8	Duration of stay at hospital after procedure	1	11	88
9	Alternative way of suggested procedure	20	23	57
10	Steps of procedure	24	25	51

Perceptions of patients toward decision making for procedure were as per Table – 3. Only 61% wanted to know every information of procedure and wanted to decide by themselves while 82% wanted to know everything but letting decision left on doctor. (Table – 3)

Discussion

Informed Consent originated to protect the legal and ethical rights of the patient to improve doctor patient relationship and health care system. The most important goal of informed consent is that patient can acquire knowledge and can take proper decision suitable to him [1].

Table – 3: Perceptions of patients toward decision making for procedure.

Sr. No.	Questions	Responses of participants (%)		
		Disagree	Not sure	Agree
1	I trust and abide decision taken by doctor on behalf of me without any information for procedure	71	10	19
2	I want to know every information of procedure but doctor will decide finally	10	8	82
3	I want to know every information of procedure and will decide myself	16	23	61

Most of the patients want to aware of their legal and ethical rights but proper guidance and availability of hands on information is lacking. Before any procedure patient must know reason, benefits, risk, alternative procedure, its risk and benefits, limitations after procedure and cost of procedure [9].

Several studies have shown that written information in the language patients can understand has beneficial effects. Patient information sheet in vernacular language must be necessary before obtaining their informed consent [10, 11].

The present study revealed that 88% patients wrongly believed that informed consent was a legal requirement. 77% thought that signing the consent meant waving their rights to any compensation. Most (81%) of the patients thought that they can't refuse procedure after signing the consent. Similar observations were also made by another study from Egypt [12].

It was found in this study that majority of the patients were interested to know about duration of the operation, possible risks and complications involved in procedure, chances of successful procedure and cost of treatment which is similar to study from New Zealand [13]. Our study showed that many patients have limited knowledge of the legal implications of signing or not signing consent forms and don't recognize written consent as primarily serving their interests for their beneficiary which is similar to study done by Akkad A [14].

Some authors noted that providing information about risks and complications causes undue and unnecessary anxiety and timidity among patients and make them weak to decide [15]. Pimentel, et al. [16] investigated the desire for information in patients with cancer and reported that most of the patients wanted to know as much as possible about their illness and treatment to have long survival [17].

Some patients stated that doctor must take decision on behalf of them and take all responsibility [18]. Because of this mind set of people some time informed consent is not serving its actual purpose. Many times information given to the patients is inadequate and many times it may be over loaded beyond their capacity to digest it. Beresford and colleagues argued that some patients want little or no information about therapeutic risks and that the standard of the disclosure of the reasonable patient should not be applied to them [19-22].

Different types of patients depending upon their education, socio-economical status, living status etc. can vary among their perceptions but education to them is very much necessary to bring equality.

Conclusion

The study concluded that there is a wide gap between actual concept of informed consent and perceptions of patients for the same. Patient awareness programs must be conducted by appropriate authority with help of media and

television to improve their knowledge and preserve their rights.

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