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Research Article

Are we requesting the right consent?

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ABSTRACT

Background: Medical treatment can only be administered with consent of a competent patient. Giving the treatment without consent is failure to respect patient's autonomy; violating an individual's right to self-determination.
Methods: We conducted a cross sectional study to evaluate the consent forms from various hospitals. Consent forms of 372 out of 750 medical institutes in Nagpur were evaluated under 20 ethical and medico legal aspects of an ideal consent form.
Results: Most of the consent forms lack important clauses of an ideal consent form that can go against the treating doctors in the court of law.
Conclusions: Doctors need to be trained to design a consent form. They need to be made aware of the medico legal rights of the patient. The consent form is for the patients to acknowledge that the nature and purpose of treatment has been fully explained, understood and consented to. Remember patients never consent to doctor's negligence but only to risks and complications.

Keywords: Consent, Medico legal

INTRODUCTION

In modern days, the doctor is no longer held in high esteem. The faith in the healer has been slowly waning. The gentleman's agreement no longer holds true and every agreement is now in black and white. Today the doctor is viewed with suspicion and the doctor too safeguarding himself or herself prefers to have a consent for everything. Consent is an ethical principle. Medical treatment can only be administered with consent of a competent patient. Giving the treatment without consent is failure to respect patient's autonomy; violating an individual's right to self-determination. Any medical treatment given without consent is an action for trespass where damages are payable.

Patients are admitted in hospitals wherein they undergo therapy in the form medications, investigations which could be invasive non-invasive or interventions or surgeries. In all the above mentioned situations the patient has to agree to the required therapy. When a patient walks into a doctors' office, it is understood that it is a voluntary act and he/she implies that he/she is willing to undergo a clinical examination by the doctor and accept the treatment prescribed thereof. But if a person is admitted in a hospital, the person has to be informed at every step the findings of the clinical examination and consent obtained for further therapy. This is done by obtaining his/her signature to consent to any treatment. This important piece of paper is called a consent form.

METHODS

We conducted a cross sectional study to evaluate the consent forms from various hospitals. We designed an ideal consent form which covered 20 ethical and medico legal aspects. This was validated by experts in the clinical field, lawyers and medico legal expert. In the city of

Nagpur there are about 750 registered health care institutes that include nursing homes, multispecialty hospitals, corporate hospitals and hospitals attached to medical colleges. We requested the doctors / administrative officers permission to evaluate the consent forms which they asked the patients to sign whenever the doctors intended to intervene. Of the total 516 medical institutes where patients are admitted which we approached, 372 permitted us to look at their consent forms.

Review of literature

Historical background

In 5th century B. C. Hippocrates stated "Primum non nocere" that is first do no harm.

In the year 1900 Dr. Walter Reed conducted his yellow fever experimentation with Spanish immigrant workers and soldiers in Cuba that confirmed the transmission of yellow fever by mosquitoes. The research work with the disease under Reed's leadership was largely responsible for stemming the mortality rates from yellow fever during the building of the Panama Canal.[1]

The Tuskegee syphilis experiment was an infamous clinical study conducted between 1932 and 1972 by the U.S. public health service to study the natural progression of untreated syphilis in rural African American men who thought they were receiving free health care from the U.S. government. They were never told they had syphilis, nor were they ever treated for it. The 40-year study was controversial for reasons related to ethical standards; primarily because researchers knowingly failed to treat patients appropriately after the 1940s validation of penicillin as an effective cure for the disease they were studying. Revelation of study failures by a whistleblower led to major changes in U.S. law and regulation on the protection of participants in clinical studies.[2]

In 1947, the judges in Nuremberg delivered their verdict in the "doctors' trial" against Karl Brandt and 22 others. These trials focused on doctors involved in the human experiments in concentration camps. The suspects were involved in over 3500000 sterilizations of German citizens.[3]

The scientist may have felt they are working for the progress of science, but they had violated a human right. The experiments were conducted on humans who could not express themselves or refuse to be part of the experiment. The exploitation of humans in compelling situation led to the declaration of Helsinski and a code of conduct has been drawn up both for the patients admitted as a routine for therapy and for experimentation studies.[4]

Experiments on humans or interventions on a patient should be done with a free will of the patient and for the person to express a free will, a complete knowledge of methods of intervention are a must. To obtain permission of patient, a signed consent form is a must.

Consent in Indian Penal Code

Legal definition of consent: The term consent is defined as when two or more persons agree upon the same thing in the same sense they are said to consent as per the definition of consent given in section 13 of Indian contract act, 1872.

For the purpose of clinical examination diagnosis and treatment consent can be given by any person who is conscious, mentally sound and is above twelve years of age as per section 88 and 90 of the Indian penal code, 1860.

Medical professionals are reminded that consent is taken under section 13 of the Indian contract Act, 1872. This Act, however also provides under section 11 that only those persons above 18 years of age are competent to enter into a contract. Since doctor-patient relationship amounts to entering into a contract, it is advisable that consent should be obtained, specially written consent, from parents/guardian of a patient who is below 18 years so that validity of the contract is not challengeable.

Under section 53 (2) of the code of criminal procedure, whenever a female is to be examined, it shall be made only by or under supervision of a female doctor.

For medical treatment: the voluntary and continuing permission of the patient to receive a particular treatment, consent is based on adequate knowledge of the purpose, nature, likely effects and risk of that treatment, including the likelihood of its success and any alternative in it.[5]

Section 10 of Indian contract Act, the consent should be free consent.

Consent in the context of the practice of medicine concerns the following three situations:

1: Examination of the living patient for the purpose of diagnosis and subsequent treatment.

2: Examination of living person for medico legal purpose.

3: Post-mortem examination and removal of tissue for transplantation.[6]

Depending upon the circumstances in each case, consent may be implied, expressed or informed.[5]

1. Implied consent: The fact that a person comes to doctor for an ailment implies that he is agreeable to medical examination in the general sense. This, however, does not imply consent to procedures more

complex than inspection, palpation, percussion and auscultation and routine sonography.

2. Express consent: Anything other than implied consent is expressed consent. This may be either oral or written. Express oral consent is obtained for relatively minor examinations or therapeutic procedures, preferably in the presence of disinterested third party. Express written consent is to be obtained for: a) all major diagnostic procedures, b) general anesthesia, c) for surgical operations, d) intimate examinations, e) examination for determining age, potency and virginity, and in medico legal cases.

3. Informed consent: All information must be explained in comprehensible non-medical terms preferably in local language about the diagnosis, nature of treatment, risk involved prospects of success, prognosis if the procedure is not performed and alternative methods of treatment. The doctors duty to disclose is subject to the exceptions: a) if the patient prefers not to be informed and b) If the doctor believes in the exercise of coming to a sound medical judgment, that the patient is so disturbed or anxious that the information provided would not be processed rationally or that it would probably cause significant psychological harm.

Validity of a consent form: The salient characteristics of a valid consent form are[7]

1: Consent must be voluntarily given in writing by the patient out of his or her free will after

a) Understanding the necessity, nature and limitation, consequences and the risk of the treatment.

b) Realizing the possible complications and risk of the treatment and the anesthesia and

c) Taking into consideration the alternative modes of treatment if any.

2: Such informed consent must be obtained in the presence of a witness who should affix his or her signature to state so, prior to every procedure.

3: Consent given in medical profession should be free will and accord and not by fraud, mistake or misrepresentation.

Invalid consent form: The following situations will make the consent forms invalid.[8,9]

1. If it is obtained by fraud, by misrepresentation as to the nature of the procedure or by undue influence or by threat of violence.

2. The consent was obtained when the patient was under sedation.

3. If there is failure in giving information and sufficient disclosure regarding the procedure?

4. If the consent is given by the minor since he is not legally competent to give it.

5. If the consent is given by a person of unsound mind or mentally handicapped.

6. If the procedure performed by the doctor is substantially different from the one for which consent was given or the procedure performed exceeds the scope of consent.

7. If the different physician than the one to whom consent was given, carries out the procedure.

8. If the consent is a blanket consent.

9. If the consent is obtained for a criminal act like criminal abortion, euthanasia etc.

10. If there is insertion of a clause in a standard contract or consent form exonerating the hospital, doctor or the staff working under them for liability arising out of any negligence which may occur.

Situations where consent may not be obtained[6,7,9]

1. Medical emergencies need to save life or future health.

2. In case of a person suffering from a notifiable disease.

3. Immigrants.

4. Members of armed forces.

5. Handlers of food and dairy milk.

6. New admission to prison.

7. In case of a person where a court may order for a psychiatric examination or treatment.

8. When a person is brought for medical examination by police like a case of alcoholic intoxication, sexual assault. No consent of the patient is required for the medical examination but no treatment can be enforced without consent of the patient.

9. In case of arrested person brought by police to take blood sample or sample of hair or anything required for evidence, even reasonable force can be applied to obtain sample.

We drafted a consent form and validated it with the help of experts in the clinical field, lawyers and medico legal expert. As a result of the deliberation an ideal consent form should have the following characteristics.[7,10]

1. The diagnosis is clearly written.
2. The name, nature and purpose of the proposed treatment or procedure are specified.
3. The risk and benefits of proposed treatment or procedure are explained.
4. Alternative procedures and treatment are offered or reflected in the form.
5. The risk and benefits of the alternatives are mentioned.
6. The patient right to refuse treatment or procedure as an alternative are stated.
7. The risk and benefit of not receiving treatments or undergoing procedures are also given as an option.
8. Name and signature of the patient or legal guardian are clearly written.
9. Name of the hospital.
10. Name of all practitioner's performing the procedure and individual significant tasks if more than one practitioners are shown in the form.
11. Date and time consent is obtained.
12. Statement that procedure was explained to the patient or guardian.
13. Signature of professional witnessing the informed consent along with the name.
14. Name, signature and statement from person or interpreter who explained the procedure to the patient or guardian in a way they could understand is stated.
15. Approximate cost of the treatment is included in the checklist.
16. The relative chances of success or failure of the procedure are mentioned.
17. The risk of death due to procedure must be explained in terms understandable to the patient.
18. The consent form should not contain blanket statement absolving the doctor of all bad outcomes.
19. Forms in English.
20. Forms in vernacular language (Hindi or Marathi).

RESULTS

100% of the medical institutes in their consent forms have the name of the treating doctor, statement that procedure was explained to them and the signature of the patient or the guardian. All of the medical institutes had their consent forms in English.

93.3% of the hospitals had consent forms where the name of the hospital and date, time when the consent was taken, was denoted. An equal number of consent forms were in vernacular language either in Hindi or in Marathi.

The same percentage of the consent forms mentioned about the risk and benefits of the proposed treatment or procedure and signature of the professional witnessing it.

86.6% of the consent forms had mentioned the name, nature and purpose of the proposed treatment.

Inspite of the repeated instructions to the doctors during their study days 86.6% still feel that if they include a statement "we will not held the treating doctor responsible" they can escape a medico legal tangle.

66.6% of the consent forms had the name, signature and statement from person or interpreter who explained the procedure to the patient or guardian in a way they could understand.

53.3% of the consent forms had the diagnosis written on it.

46.6% of the consent forms mentioned other modalities of the treatment which would include non-surgical management for a surgical condition or various other modalities of the treatment available for a particular disease.

40% of the consent forms stated the risk and benefit of the alternative treatment.

Only 33.3% of the consent forms mentioned the right of the patient to refuse for the proposed treatment or procedure.

An equal number of the consent forms mention death due to the proposed treatment or procedure was discussed.

The estimated cost for the proposed treatment or procedure was mentioned in 26.6% of consent forms.

A mere 20% of the consent forms mentioned the risk of not undergoing the treatment or procedure to the patient well in advance of the commencement of the treatment.

A meager 13.3% of the consent forms had mentioned the relative chances of success or failure of the consent forms.

Table 1: Observation.

No.	Observation	
1.	Name of the hospital.	93.3%
2.	Name of all practitioner's performing the procedure and individual significant tasks if more than one practitioner's.	100%
3.	The diagnosis written.	53.3%
4.	Date and time consent is obtained.	93.3%
5.	The name, nature and purpose of the proposed treatment or procedure.	86.6%
6.	Statement that procedure was explained to the patient or guardian.	100%
7.	Name, signature and statement from person or interpreter who explained the procedure to the patient or guardian in a way they could understand.	66.6%
8.	The relative chances of success or failure of the procedure.	13.3%
9.a	The risk and benefits of proposed treatment or procedure.	93.3%
9.b	The risk and benefit of not receiving treatments or undergoing procedures	20%
10.	Death due to procedure.	33.3%
11.	Alternative procedures and treatment.	46.6%
12.	The risk and benefits of the alternatives.	40%
13.	The patient right to refuse treatment or procedure as an alternative.	33.3%
14.	Approximate cost of the treatment.	26.6%
15.	Name and signature of the patient or legal guardian	100%
16.	Signature of professional witnessing the informed consent.	93.3%
17.	Blanket statement absolving the doctor of all bad outcomes.	86.6%
18.	Forms in English.	100%
19.	Forms in vernacular language (Hindi or Marathi).	93.3%

DISCUSSION

No man of professional skill can justify the substitution of the will of the surgeon for that of the patient.

Consent is not merely a form. It is patient's authorization for diagnosis and treatment.

A doctor has no right to do anything to a patient without his or her consent except in case of an emergency when he or she must exercise his or her discretion.

Consent plays an important role in the criminal law in the sense that it can exonerate or extenuate a criminal act. The concept is primitive one and is based upon the Roman maxim 'volenti non-fit injuria' i.e. he who consents cannot complain of it.

With time the consent of a patient is evolved to an informed consent where consent is taken on as a written document with all modalities of treatment explained and alternatives suggested. Hospitals - corporate institutions or individuals are doing a fairly good job in providing health care yet documentation of most aspects of the medical treatment is miserable as our study shows. Doctors need to inform patients in clear terms not only about the plan of treatment but also about the risks and benefits including possibility of death. The patient should also be made aware of the alternative treatments available. It is important that the risk and benefit of alternative treatment are also known to the patient. The risk s of not undergoing treatment should also be known to the patient. It is deplorable that nearly 75% of doctors have not discussed the financial aspects of the treatment. Contrary to confidence shown outside their offices, nearly half of the doctors fail to write the provisional diagnosis on the consent forms.

CONCLUSION

Doctors need to be trained to design a consent form. They need to be made aware of the medico legal rights of the patient. The consent form is for the patients to acknowledge that the nature and purpose of treatment has been fully explained, understood and consented to. Remember patients never consent to doctor's negligence but only to risks and complications.

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