Consent

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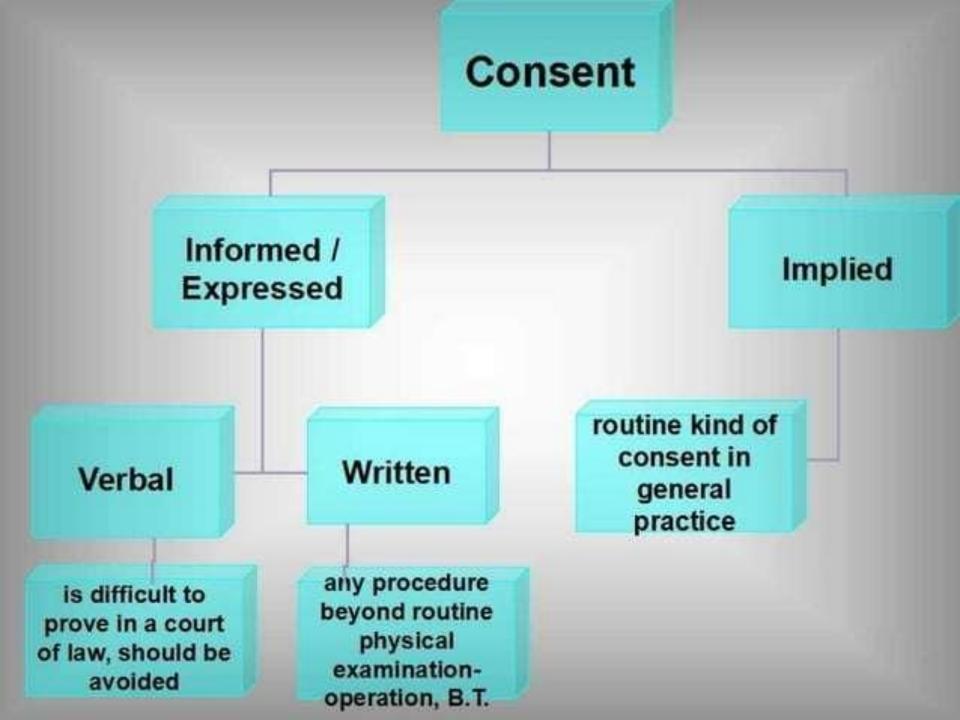
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Consent

Consent means voluntary agreement, compliance or permission.

Consent

To be legally valid it must be given after understanding what it is given for and of risks involved.



Informed / Expressed consent

After understanding of the patient..... (a) the nature of condition, (b) the nature of proposed Rx or procedure, (c) the alternative procedure, (d) the risks and benefits involved in both, (e) the potential of risk if Rx not taken, (f) the relative chances of success or failure in both.

IMPLIED CONSENT

is given when:

- a person knows that he can either agree or refuse to a R_x or operation,
 - (2) knows or has been informed by the physician as to what is to be done,
 - (3) then cooperates with the physician, means that he has impliedly consented in words.
 - e.g. the consent given in routine clinical practice.

RULES OF CONSENT

- 1) Most of the rules of consent are as per S. 87, 89, 90, 92 of the IPC and S. 53(a),(b), S.54 of CrPC, MCI Regulations, 2002, besides many other Acts and laws as applicable.
- Some of the rules are as per various court judgements.

For a procedure under L.A., can expressed verbal consent be taken by a patient when s/he is unaccompanied by someone?

Preferably, no.

Expressed verbal consent should be taken in the presence of a guardian, etc. (not usually a staff of hospital)

Ideally, go for a written expressed consent. Verbal consent is difficult to prove in a court of law, should be avoided.

Where all informed consent is necessary?

Informed consent is necessary for every invasive procedure or surgery, medical examination of a person for alcohol, potency, sexual abuse, etc. but not for routine physical examination where the consent is implied.

What are the rules for informed consent?

1) Written consent should be taken for each procedure separately, and not a blanket permission for all procedures. e.g. separate consent for surgery, blood transfusion, etc.

What are the rules for informed consent?

2) Signature (if literate) or thumb impression (if illiterate- left in men, right in women) of the patient should be obtained below the consent, and the doctor taking the consent should also sign alongside the patients signature.

Can a patient, admitted on his own for a major surgery, refuse to give consent?

Can he refuse for an emergency surgery required to save his life?

What should the Doctor do?

Yes, the patient can refuse to give consent.

In such a case the patient should not be examined or operated upon against his will even if it is an emergency- **Informed refusal**.

Can a patient, admitted on his own for a major surgery, refuse to give consent?

Can he refuse for an emergency surgery required to save his life?
What should the Doctor do?

The Doctor should get the informed refusal written and signed on the case-sheet.

If the patient refuses, the Doctor should get signed by accompanying relatives/friends.

Can a child < 12 years of age give consent to be examined alone, without a guardian?

- 1) Legally, yes. But, preferably, no.
- Can give consent for examination onlyinspection, palpation, percussion, auscultation. Not for invasive procedures.
- 3) For a child < 12 years, obtain consent of guardian only. (Sec. 89 IPC)

Can a patient, admitted on his own for a major surgery, refuse to give consent?

Can he refuse for an emergency surgery required to save his life? What should the Doctor do?

If they refuse, a panel of 3 Doctors should sign the informed refusal mentioning that the patient and his relatives have refused to sign.

If the opportunity allows, record the informed refusal.

Can a child between 12 and 18 years of age give valid consent for examination and minor / major surgery?

- Can give consent for examination and noninvasive procedures and invasive procedures not harmful to life.
- 12 18 years → obtain consent of both child & guardian.

Can a person > 18 years of age give valid consent for examination and minor / major surgery?

- 1) Yes.
- 2) Can give consent for any type of examination, procedure or surgery.
- 3) For > 18 years of age, obtain consent of patient only. (S. 87 IPC)

What is invalid consent? Which consent is not valid (partly answered in S. 90 IPC)?

- 1) intoxicated,
- 2) insane,
- 3) consent given under threat or fear of injury,
- 4) due to misunderstanding of a fact,

What is invalid consent? Which consent is not valid (partly answered in S. 90 IPC)?

- 5) without understanding by th patient the nature of the procedure undertaken,
- 6) without understanding by the patient the likely consequences / outcome of the procedure undertaken,
- without understanding the likely alternatives to the procedure,

What is invalid consent? Which consent is not valid (partly answered in S. 90 IPC)?

- without understanding the complications or associated risks,
- without understanding the likely outcome if procedure is not undertaken,
- 10) without understanding the relative chances of success or failure of procedure undertaken and its alternatives.

Who can give consent at school, in an emergency, when parents are not available?

- 1) School teacher- Loco Parentis.
- 2) The consent is not required in an emergency (S.92 IPC).

Who gives consent for vaccinating a child or adult?

Law- statutory authorization.

From whom should the consent be obtained for contraceptive sterilization?

Both- wife and husband.

For conducting M.T.P., is consent of husband / partner necessary?

- No. Husband's consent not necessary.
- Written consent of the woman only, is required as per the MTP act.
- 3) If minor → guardian's consent.
- Cannot be done on request of husband if woman not willing.
- 5) No proof of age required.

For conducting M.T.P., is consent of husband / partner necessary?

- 6) In case of rape → can be done without police complaint.
- 7) Professional secrecy is to be maintained.
- 8) < 12 weeks of pregnancy → can be done by a single doctor.
- 9) B/w 12 to 20 weeks → opinion of 2 doctors is must but can be done by any one doctor.
- 10) In an emergency → by any Doctor, in an unrecognized centre as well.

A person who had pledged his organs for donation & transplantation has died, how should we proceed to harvest the organs so pledged?

Such organs can be removed only with the consent of the legal heirs or guardians.

From whom should the consent be obtained to find out the cause of death as in a Pathological autopsy?

Consent of legal heirs is required.

Can we proceed for a post-mortem examination / Medico-legal autopsy if the relatives refuse to give consent?

Consent of relatives is not required- Law provides the consent (statutory authorization) for removal of anything from the cadaver for examination purposes.

A research has been undertaken. Can a photograph / case report of a patient be published without his consent?

Consent is needed if identity is to be revealed, not needed otherwise.

For photographs, cover the eyes.

Obtain informed consent as per ICMR guidelines.

Is consent of patient sufficient to proceed for IVF?

Consent of patient, spouse and donor.

Can a patient be discharged from the hospital if he demands so, despite the patient's condition not fit enough to be discharged as per the Doctors' assessment?

A patient cannot be detained against his will. If he demands discharge, he should be discharged with the advice 'Discharge-onrequest' or LAMA.

 Unconscious person / Emergency situationno need to obtain consent if no one is accompanying.

Or, obtain consent of accompanying persons. If they refuse to consent, even then you can go ahead with the treatment or surgery without onus of lack of consent on part of the Doctor.

To be still safer, should obtain three other Doctor's consent of different specialities.

- Otherwise, there is no real need no need to obtain consent in such a situation.
- One is protected by Sec.92 IPC (act done in good faith for benefit of a person, without consent).
- S.92 IPC applies in 3 situations- can't give consent, incapable of giving consent, no guardian available.

4) Provision for a counselling room with CCTV (with audio recording facility) for consent/video consent, the outside of which clearly mentions a signboard 'You are under CCTV surveillance'.

Is recording consent in a counselling room with CCTV installed, legal?

- 1. If the person has been apprised before entering the room that this room is under CCTV surveillance, there is nothing illegal about it in order to video-record consent.
- 2. Counselling room can be used for explaining poor prognosis of patient to the relatives or for obtaining high-risk consent or if the patient's relatives refuse to sign high-risk consent.

How should the consent be recorded?

For a consent to be valid, it should be in vernacular language, his own handwriting, or printed in a language that the patient can read (or understand, if illiterate), given by free will of person, free from threat, in full possession of his senses.

Is high-risk consent legal?

Yes

Is 'Death-on-table' consent legal?

Yes

Should a Doctor fully disclose the facts of a case or a procedure planned to be undertaken (full disclosure) to the patient?

1) Full disclosure- the facts which a doctor must disclose depend on the normal practice in his community and on the circumstances of the case.

Should a Doctor fully disclose the facts of a case or a procedure planned to be undertaken (full disclosure) to the patient?

2) The doctor can decide how much should be disclosed to the patient, depending upon patient's personality, level of education, mental state, etc.

Fearing decline in signing consent by a patient, can a Doctor take it upon him to disclose only the positive facts that suit his decision to perform a procedure and not disclose the harmful ones from a patient, in order to perform the procedure that he wants?

- 1. Abuse of medical knowledge so as to distort the doctor-patient relationship in such a way that the patient is deprived of his autonomy, or of his ability to make a rational choice; in the context of disclosure to the patient- Paternalism.
- 2. Doctor should disclose only one or two important complications, not all, to enable the patient to take decision as regards the procedure to be performed.

- 3. The Doctor need not explain remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent (as outlined by Supreme court in Samira Kohli case, 2008).
- 4. But while writing in consent form, all complications, alternative procedures, harm in not doing the procedure, all theoretical risks involved should be mentioned.

Can there be a common consent for diagnostic and operative procedures? Can there be a common consent for a surgery and an additional surgery?

Yes.

There can be a common consent for diagnostic and operative procedures where they are contemplated.

There can also be a common consent for a particular surgical procedure and an additional or further procedure that may become necessary during the course of surgery (as outlined by Supreme court in Samira Kohli case, 2008).

Who is eligible to sign the consent form?

Patient > Spouse > Father > Mother > Son > Daughter > Guardian > Any relative > Any friend > Any accompanying person > Any un-related person > Any other patient.

Hospital staff should not be made a witness.

Is consent required for blood transfusion?

Consent for blood transfusion is mandatory if any procedure is carried out which may lead to bleeding whether anticipated or not. And it has to be an informed consent.

Consent for Blood transfusion cannot be under blanket consent taken for the procedure.

Important judgements regarding Consent

- Samira Kohli Vs Dr Prabha Manchanda, Supreme Court, 2008
- 2. Saroj Chandhoke Vs Ganga Ram Hospital & Dr S.K.Bhandari, National Commission, 2007

Thank you!