CHAPTER
5

Informed Consent for Surgery: Guidelines and Best Practices

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One of the primary causes of litigation in the medical field is the failure to obtain proper consent. Securing informed consent is crucial in minimizing legal disputes and ensuring ethical medical practice. Any medical intervention, especially those involving physical integrity (i.e. surgical or invasive procedures), is unlawful without proper consent. Surgeons may be held liable under civil and criminal law if consent is not appropriately obtained.

Patients have a legal right to make decisions about their medical care and must be informed of all relevant details to make an informed choice.

TYPES OF CONSENT

Implied Consent

Implied consent is not explicitly given but is inferred from a patient's actions and the context. It is applicable in the following situations:

- Outpatient department (OPD) visits for routine checkups unless an invasive procedure is required.
- Non-invasive diagnostic or therapeutic procedures.
- Routine investigations such as blood tests.

Expressed Oral Consent

Expressed oral consent is necessary for detailed examinations and treatments. It is obtained by verbally asking the patient for permission before performing a procedure. However, no written consent is required in these cases.

Written Informed Consent

For any surgical or invasive procedure, informed written consent is mandatory. This process involves:

- Providing adequate information about the procedure, potential benefits, and complications.
- Ensuring that the patient fully understands the procedure before agreeing.
- Avoiding too much or too little information, as both can lead to confusion.

Who can Obtain Consent?

The consent must be obtained by:

- The **surgeon** who is performing the procedure.
- A **reliable and competent deputy** or assistant.

Legal Requirements for Consent

Age and Mental Competence

- *Patients aged 18 years and older:* Consent must be obtained from the patient directly. Do not take consent from family members unless the patient is legally incompetent.
- For children under 12 years, consent must be obtained from a parent or guardian.
- *Children aged 12–18 years:* Consent must be obtained from both the patient and the parent or guardian.
- *Minors or incompetent patients:* 'Proxy' consent must be obtained from a responsible adult.

Proxy Consent

Proxy consent is given by a competent adult responsible for the patient, including:

- A spouse or blood relative (preferably a first-degree relative, but not mandatory).
- Biological parents or guardians.
- Any one parent (even if the other disagrees).
- A non-relative (such as a teacher or warden) in emergency cases.
- The Medical Superintendent or Head of the hospital, if no guardian is available.

Timing and Process of Consent

- Consent should be obtained well before the procedure to allow the patient time for consideration.
- Avoid taking consent on the day of surgery, as patients may feel pressured.
- Explain the procedure in simple, non-medical terms. If there is a language barrier, use a legally competent translator/interpreter who must sign the consent form.

Essential Information for Patients

Patients must be informed about:

- The type of surgery or procedure.
- The intended benefits and expected outcomes.
- Common risks and complications (excluding rare ones).
- The prognosis and possible outcomes.
- Alternative treatment options, their advantages/disadvantages, and the recommended option.
- The consequences of refusing treatment.

Patients must also be made aware that:

- Unexpected situations during surgery may require additional or alternative procedures.

- Removed tissues, fluids or organs may be sent for pathological examination.
- The name of the lead surgeon and anesthetist should be mentioned.

SPECIAL CONSENT CONSIDERATIONS

Multi-stage Treatments

For procedures conducted in multiple stages:
- A single, comprehensive consent should be obtained, detailing each stage.
- Each stage must be listed separately in the consent.
- Patients can withdraw consent at any time.
- If significant changes arise, fresh consent is required.

High-risk Consent

A high-risk consent is necessary when:
- The procedure is complicated or critical.
- The patient has co-morbid conditions that could affect the surgery.
- The patient is in a crucial state or high-risk category.
- A legally competent, independent witness should be present.

Consent for Illiterate Patients

Obtain a thumb impression for patients unable to sign (left-hand for males, right-hand for females).

Emergency Situations

- If possible, obtain direct consent from the patient.
- If the patient is unconscious or incompetent, obtain proxy consent.
- Inform hospital authorities and document the life-threatening nature of the emergency.
- Avoid obtaining blanket consent at admission.

Anesthesia and Blood Transfusion Consent

- Specify the type of anesthesia (general, local, epidural, spinal, etc.).
- Obtain separate, specific consent for blood transfusion. In emergencies, transfusion can be administered without prior permission.

Refusal or Delay in Consent

If the patient or attendants delay or refuse consent:
- Document the reason for refusal.
- Explain and record the consequences of refusal or delay.

A template of consent, with the minimum compulsory requirement, is as follows:

CONSENT FORM Proforma

'PATIENTS INFORMATION'

NAME:..... GENDER: (M/F)..... AGE: .....

CONTACT NO.:..... ADDRESS:.....

IPD NO.: .....

SURGEON IN-CHARGE: .....

ANESTHETIST IN-CHARGE: .....

PROPOSED TYPE OF ANESTHESIA: .....

DIAGNOSIS: .....

TYPE OF SURGERY: .....

ALTERNATIVE OPTION: .....
.....

Consequences of not operating .....
.....

The nature and purpose have been explained to me by concerned doctors clearly in a language I understand. I also declare that I have explained all the potential common complications, risks, and benefits of the proposed procedure/surgical treatment. I am giving this consent voluntarily, free of charge, without any pressure.

Patient signature: ..... Date: .....

'ATTENDANT INFORMATION'

NAME: ..... GENDER: (M/F) ..... AGE: .....

CONTACT NO.: ..... RELATIONSHIP WITH PATIENT: .....

Attendant signature: ..... Date: .....

I hereby declare that I have explained the case/procedure to the patient in detail and answered all the queries to the patient's satisfaction in the language he could understand.

NAME AND SIGNATURE OF DOCTOR

Witness: ..... **Date and Time:** ...../.....

AUDIO-VISUAL CONSENT

Importance of Audio-Visual Recording

Audio-visual (AV) recording enhances legal protection for both doctors and patients. It is mandatory for clinical trial participants and should be implemented for complex procedures.

Guidelines for Audio-Visual Recording

- Preserve AV recordings for a minimum of five years.
- AV consent cannot replace written consent.
- The patient's next of kin (NOK) should be present.
- An impartial witness (IW) should be present if the patient is illiterate.

Audio-Visual Recording Procedure

- *Consent room setup:*
  - Use a private, quiet room near the operation theater.
  - Ensure the presence of:
    - The surgeon or a reliable deputy.
    - A hospital witness (e.g. a nurse).
    - The patient/NOK/representative/IW.
  - Identify all participants by name, age, and relationship to the patient.
  - Obtain prior consent for the AV recording itself.
  - Record the patient reading the consent form.
- *Explanation and documentation:*
  - The doctor must clearly explain:
    - The condition is being treated.
    - The procedure, risks, benefits, and alternatives.
  - Open-ended questions should be asked to confirm patient understanding.
  - Ensure that the patient's signature or thumb impression is recorded.
  - Show the signed consent form on the AV recording.
- *Preservation of AV consent:* The AV recording should be securely stored in hospital records for at least five years.

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