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INFORMED CONSENT IN MEDICAL PRACTICE

Principles and Conventions

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Forewords
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CHAPTER 2

Informed Consent in Special Circumstances

MEDICAL EMERGENCIES

While treating a patient in emergency situation, there is no any impediment or hindrance for a doctor, for urgent treatment of such patient. There is unanimity in various court decisions that the doctors should prioritize lifesaving procedures in cases of emergencies.

Preservation of life, saving life and duty of care are established as absolute, non-negotiable and supreme constitutional obligations of the medical profession and the state. All legal or medicolegal formalities of police information or consent or statements or police investigations or professional fees, etc. take a back seat. So, doctors in government service or private practice should immediately attend to the patient in emergencies, whether medical or medicolegal.

This obligation of the doctors is only to the extent that they tackle the emergent situation. Once the patient is stable, further clinical management should be done only with the expressed written informed consent of the patient. Any emergency surgical procedure can be carried out without consent of the patient, but it should be limited only to the extent of saving the life or limb of the patient. Doctors should avoid the temptation to carry out any additional surgical procedure (while the patient is anesthetized) which is not "lifesaving," merely because it is "convenient" to do. Such procedures should wait and should be carried out only with the consent of the patient later on.

PREGNANCY

In the early months of pregnancy, its diagnosis may be difficult, especially so when the lady tries to conceal it. Before examining any pregnant lady, the doctor must obtain her written and witnessed informed consent.

The procedure for examination, including that of intimate examination should be explained to the patient in detail [including the information about the need to undress, need to inspect and palpate, need for per vaginal examination, pelvic ultrasonography (PV USG), etc].

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All available means of diagnosing pregnancy in early weeks or months should be explained including the chances of success and failure to diagnose by such means.

The planned procedure or test and its chances of success and failure should be informed.

All precautions as mentioned above under "intimate examination" should be followed. The examination should always be witnessed by a female witness. Such witness should be present in the examination room throughout the process of examination. The witness should not leave the examination room under any pretext, till the doctor is examining the lady. She should only leave the room after the doctor leaves.

The results of the tests should only be disclosed or reports handed over to the adult patient ONLY, and not to anyone else including her husband or parents or siblings or any other relative. She can disclose it to them herself. If patient is below18 years, then the provisions of Section 19 of the Protection of Children from Sexual Offences (POCSO) Act shall apply, whereby the doctor is duty bound to inform the police (even if the patient and her parents do not wish to inform).

DELIVERY

Before obtaining consent for delivering a lady, the doctor should plan the process of delivery as per the requirement of the case.

Applying his or her knowledge of obstetrics, the doctor should decide if he plans to deliver it vaginally or give it a trial labor first and then decide or if he plans to perform forceps delivery or a cesarian section, etc.

The doctor should also anticipate any complications in view of patient's past history, her diabetic status if any, cephalopelvic disproportion, lie of the fetus, cord around neck, existence of placenta previa or accreta or endometriosis and its grade, presence of fetal distress, any systemic disease in the mother, anemia, bleeding tendencies, previous lower segment cesarean section (LSCS) or any other disease/ailment/factor/event, etc. that might affect the course of planned delivery. Doctor should accordingly investigate the patient during her antenatal care (ANC), to confirm or rule out such factors that are essential in deciding the method of delivering the lady.

Accordingly the scope of consent and the contents of consent form should be decided and explained to the patient. Once such informed consent is obtained from the patient, the doctor should proceed as per the procedure decided and explained to the patient in the consent form.

STERILIZATION

- Doctors should not commence the procedure unless they ensure that an informed written consent is provided voluntarily by the patient and

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that her informed choice about the method of contraception is clearly documented therein.

- The following information must be given to the patient before she/he signs the consent form for sterilization operation:
  - All the available methods of family planning.
  - That it is a permanent method to prevent future pregnancies.
  - It being a surgical procedure, there is possibility of complications including failure. Further management may be required in case of any complication.
  - Sexual pleasure, ability or performance is not affected by the sterilization procedure.
  - Patient's ability to perform routine day-to-day functions or strength is also not affected.
  - The sterilization procedure does not provide any protection against any sexually transmitted diseases (STDs).
  - That the sterilization surgery can be reversed, however the success of reversal surgery cannot be guaranteed.
- Though intrauterine contraceptive device (IUCD) is one of the most effective types of reversible contraception, however, there are chances of its failure. The failure of IUCD is mostly due to its partial or complete expulsion, which goes undetected. If such pregnancy has not advanced beyond 20 weeks of gestation and if the lady wishes to terminate it, then it can be terminated after the doctor documents an informed written consent of the lady for medical termination of pregnancy (MTP).
- *The consent of the spouse is not required for sterilization.*
- While deciding the issue of "validity of consent" for sterilization, three aspects need to be considered:
  1. Indication for sterilization, whether primarily for sterilization or incidental to surgery for treatment of some other underlying disease
  2. Competency of the patient to consent
  3. Failure of sterilization operation.
- If the sterilization is necessitated during the course of treatment for other serious underlying diseases, e.g. tumor in testes or uterus, generally there are no medicolegal issues provided a duly informed consent is obtained from the patient prior to such surgery.
- The question of spousal consent also generally does not arise in sterilization operations which are incidental to another surgery for underlying disease. However, it might be an issue in cases of primary sterilization. A competent adult woman is entitled to consent to or dissent from medical treatment for herself whether she is married or not. Even though, the consent of the spouse is not required for sterilization, ideally, it should be sought after the patient provides his or her consent to

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bring him or her into discussion. Though the spouse does not have a right to veto in such decisions of sterilization by the patient however, she/he might consider this as a ground for divorce on account of mental cruelty, which will be decided by the courts on the facts and circumstances of each individual case.

- Competency of an individual to consent may be by reason of immaturity or mental incapacity, which will be decided as per the principles discussed in Chapter 1 of this treatise. Two important difficulties in deciding the competency or otherwise are, first, what constitutes the incompetent's "best interests" and, second, as to what distinction, if any, is to be made between his or her therapeutic and social needs.
- The most important medicolegal hazard in sterilization operations is about their failure as a method of contraception. Sterilizing operations cannot always guarantee infertility. Some techniques are more efficient than others but, in general, the certainty of success is related proportionately to the extent of mutilation. The ethical problem thus resolves itself into balancing the immediate effect against the possibility of a later wish to reverse the procedure–say, on remarriage or on the death of an existing child. This poses for real dilemma.
- The success rate for reversal of sterilization by vasectomy in the male is unlikely to be better than 25% and many surgeons would decline to perform an operation that was specifically limited by the patient to one that could be undone. Reversal in the female is likely to be more successful–up to about 75%–but the original operation must have been of limited extent; sterilization techniques that eliminate the possibility of failure must be regarded as irreversible.
- It is the word "Irreversible" that has, in fact, been at the root of many actions in tort or delict that have followed pregnancies after operations for sterilization, patients who were told the operation was irreversible have contended that this meant they could never have any more children while surgeons maintain that it refers only to the surgical possibilities. There is, in fact, always a small risk that nature will circumvent the operation and reestablish path for the gametes.
- Hence, the majority of claims in negligence for failed sterilization depend not on the performance of the operation but on the degree of warning of failure that was given, and on the consequential question—would the patient have taken contraceptive precautions had he or she been informed of the risk? Essentially, the cases are exercises in "*informed consent*".
- With a sound technique competently performed, the risk of pregnancy after female sterilization is very small indeed, but not nonexistent. Sterilization in the male is not so straight forward. When the subjects are tested for the presence of sperm in the ejaculate, it is found that a small

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number of motile organisms are still present 6 months after the operation in some 40% of the men treated. Very occasionally, sperm are found later in those who were apparently sterile 3 months after the operation but, in these instances, the organisms are probably dead. The most serious complication is spontaneous recanalization of the ducts which may occur in up to 1% of cases.

- All these considerations must be explained to the patient and to the spouse *before consent can be valid*. Having done so, the usual rules covering medical negligence apply, if the patient fully understood the risks, if the operation was properly performed and if the procedure was one that was accepted as proper by competent colleagues in the profession, then the mere fact of pregnancy would not be proof of negligence. The proper procedure must, however, include adequate follow-up, this consists of routine examination of the ejaculate and proof by microscopy that the correct tissue was removed.

AUDIO RECORDING

Technological advancements in the telecommunication sector in the form of high-tech mobile handsets with multiple features including those for conveniently recording of audio conversation between the caller and receiver as well that of a third person, has given rise to some ethical and legal issue. Often the patients or their relatives record their conversation with the doctors, without the knowledge of the doctors. Also, in some hospitals, it is a practice to record the information that is verbally provided by the doctors to the patient before obtaining their informed consent and also counseling sessions. Whether it is legal to record any conversation without the knowledge of the person participating in the conversation? Statutory laws in this regard are not very clear. The case will be argued and decided on the basis of provisions of Law of Torts, Article 21 of the Constitution, Information Technology Act, etc.

In *Court on its Own Motion versus State and Ors (2009 CriLJ 677), it was* held that "a sting operation by a private person or agency is, by and large, unpalatable or unacceptable in a civilized society," and "normally, if a private person or agency unilaterally conducts a sting operation, it would be violating the privacy of another person and would make itself liable for action at law". In another case of *Court on its Own Motion versus State, 146 (2008) DLT 429,* it was held that "Sting operations showing acts and facts as they are truly and actually happening may be necessary in public interest and as a tool for justice, but a hidden camera cannot be allowed to depict something which is not true, correct and is not happening but has happened because of inducement by entrapping a person". In practice, courts weigh public interest against the right to privacy.

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Currently available legal provisions may not be sufficient to prohibit the recording if the conversation is recorded by one participant (without consent of the other) or by a third party person with consent of any one participant. Thus, in case of a complaint in this regard (that the conversation was recorded without consent) the courts will decide on the facts and circumstances of each case, the contents of recorded conversation, the issue of invasion of privacy and on grounds of public interest.

Doctors, while recording the counseling sessions with the patients or relatives and also the information that is provided before obtaining informed consent, should always inform the patient or relatives that their conversation is being recorded for purpose of documentation and will be a part of patient's medical record. If the patient or relatives agree, then their consent for such recording should be documented in the medical records.

CLINICAL PHOTOGRAPHY

- Now a days, photographs of patients are often captured as a part of medical records to improve documentation and medical care. Such photographs also serve a useful purpose in teaching and learning processes as well as published in professional print and e-journals. For each and every purpose mentioned here in above, the doctors are ethically obliged to obtain a detail written informed consent of the patient, for patient's protection and interest.
- Electronic media has the potential of worldwide distribution of any uploaded image of patients. This has necessitated obtaining a well-informed written consent of all the patients for all uses that will be made of medical images before capturing their photographs.
- Procedure of consent and the protocols about confidentiality that are required for patient's photographs are similar to those used for any other medical record. Thus, it is recommended that before capturing any photograph of patients, intended to be published or not and whether likely to be identified or not, should be preceded by a well-informed written consent, stating therein the possible consequences.
- If the patients are capable and competent to consent, their own consent should be obtained. In case of children and developmentally disabled, their parents can consent.
- The scope of consent for use of photographs should be broad enough to include the possibility of the photographs being used, other than for medical records, for any or all the uses, including teaching and publications. The consent should be designed so as to provide the patient an opportunity and option to choose amongst the various uses of the photograph. The fact that the photographs might reach wider audience than standard medical journals and textbooks, because of electronic medium, should in informed to the patient.

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- After capturing the image, the doctor should show it to the patient and let him know how it will appear in print or electronic media. Patients should also be informed that, once the images are placed in public domain, they cannot be removed, e.g. print media images which are already published. Patients should also be clarified that the doctors will not be responsible for further use of photographs, if someone has already downloaded the images from electronic medium.
- The consent form should include the contact details of the doctor. A copy of the consent form should be provided to the patient. In case, at any future date, if the patient wishes to withdraw the consent, the doctor should remove the photograph from display, in whatever format it appears.
- Patient should be informed that even if he refuses to consent for capturing his photographs or its use in publication, etc. his medical care will not be affected adversely.

AUDIO-VISUAL RECORDING IN CLINICAL PRACTICE

- Patient's audiovisual recordings can be used primarily for patient care or secondarily for teaching-learning process, research, etc.
- Before recording a video, the doctors should obtain informed written consent of the patient and ensure that the patients are not under any pressure to provide consent.
- The doctors should inform the patient beforehand that they are free to stop the recording whenever they wish to do so, without adversely affecting the clinical care being received by them.
- It should also be informed to patients that once consent for videography is given, he can withdraw his consent for sharing of the recording any time. However, it must be clarified to him that if the withdrawal of consent is after the recording is uploaded on any web-based platform, then its withdrawal may not be possible.
- Wherever practicable, the video recordings should be coded and anonymized before sharing for any secondary purposes. The patient must be informed as to when, how, why and where such recordings will be used.
- Before sharing any video recording in which the patient is identifiable, informed consent of the patient should always be obtained.
- All the recordings should be stored in a safe and secure place.
- Patients should be informed of the purpose and possible future use of the recordings, during the informed consent process.
- If a patient or his family wishes to film his treatment sessions, including filming you, he should obtain your consent, which you may choose to refuse.

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- Hospitals should have a policy about video recording which should include all the above aspects. Patients should be aware of it. Any use of such films by the patients or relatives, should not have any effect of an "advertisement" by the doctor, which is considered as an "unethical act" by the Medical Councils.

INFORMED CONSENT BY ANESTHETISTS

- Detail information about the anesthesia and associated risks should be provided to the patient during preanesthetic assessment sessions, preferably in the form of printed leaflets, so that the patient can refer to it later. The practice of obtaining signatures or thumb impression of the patient while she/he is being wheeled into the operation theater or just before intubation, on the dotted lines of a preprinted consent form should be strictly avoided, as it renders such "consent" invalid.
- "What, in the opinion of this patient, would be regarded as relevant, while choosing from the available treatment modalities?" Answer to this question should determine the nature and amount of information that should be provided to the patient.
- As consent is not an event, but a continuous process, one may require multiple sessions of discussion, till a truly informed consent is obtained. All such discussion sessions should be documented. Anesthetists or intensivists should explain to the patient the procedure, complications, risks, benefits, alternatives and effects of not undergoing the proposed procedure and document it all.
- Conditions like chronic pain might require prolonged course of treatment. Doctors should disclose this fact to the patient at the beginning of the first treatment session. Also, before every individual session, consent to continue should be obtained and documented. Before each individual session, the doctor should discuss and document the progress of the condition, changes in risk factors, benefits and alternatives, etc.
- If a competent and capable adult patient chooses to not to be informed about the risks of anesthesia, its consequences should be explained and the discussion should be documented. Patient may be counseled to revise his decision to not to know, but if unwilling to know the risks, the details should not be forced upon him. Conventions in this regard mentioned in Chapter 1 of this treatise should be followed.
- In an educational institutional set up, where trainee students are being trained in anesthesia, the teachers make every effort to minimize risks and maximize benefits, and should consider alternative ways of achieving the same end.
- There are situations where a patient is required to be anesthetized before his magnetic resonance imaging (MRI). Here, the radiologist should

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obtain consent for MRI and the anesthetist should obtain consent for anesthesia.

- Even if the patient is admitted on the same day of surgery, the anesthetist should ensure that he provides complete information to the patient and sufficient time for the patient to make his informed decision.
- The information provided by the anesthetist should not be guided by the proforma list but by what are the risks and their incidences that are relevant to that particular patient, and what he wants to know.
- Common components of anesthetic technique including requirement of being Nil-by-Mouth, premedication and its effects, transfers from ward to preoperative room to operative area to postoperative recovery area to return to intensive care unit (ICU) or wards, insertion of cannula, induction of anesthesia, noninvasive monitoring, intraoperative monitoring, medications, discomfort, awakening, etc. postoperative monitoring and medications should be informed. Also, in case of failure of one technique, available alternatives should be explained. Any specific aspects related to patient's condition or planned procedure including invasive monitoring and its associated risks, need of sedation, tracheostomy, intubation and ICU or critical care unit (CCU) facilities in recovery period, should also be explained.
- Side effects of anesthesia, both common and serious should be explained.
- Anesthetists should decide any particularly significant risk or complication to any individual patient, e.g. risk of damage to vocal cords during general anesthesia (GA) to a professional vocalist. In such instances, anesthetists should provide an estimate of incidence of risk. All the consent discussions should be documented.
- Considering the patient's diagnosis, planned surgical procedure, requirement for anesthesia, etc. the anesthetist should provide all relevant information to the patient and also offer the patient to ask questions. Anesthetists should reply truthfully to the patients' queries, however, replies to queries related to surgical procedures or any other aspect beyond anesthetists' capability should be avoided. Those should be directed to concerned specialists.
- All the oral discussions and information sessions should be documented, including the questions asked by the patient and replies provided by anesthetists. The consent provided by the patient should then be documented. Documentation may be done in the patient's case sheet, the anesthetic record or standard consent forms.
- Department of anesthesia may design proforma of anesthetic record to document the above discussion and information and consent. However, care should be taken that the proforma should only be in the form of a guide to the discussion and not in the form of a checklist. A checklist has

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a disadvantage that it is often merely ticked off without documenting the details of discussion.

- In certain situations like treatment of chronic pain, epidural pain relief for childbirth, etc. if a patient provides his restricted consent (refusing specific aspects of that treatment); the anesthetist/intensivist/pain specialist may respect patient's wishes. However, if he is not comfortable or not willing to provide such "restricted" treatment, then he may refuse to treat the patient, provided no additional harm is caused to the patient by such refusal, e.g. in cases of emergency. In such situations, the doctor should refer the patient to another suitably qualified doctor.

PATIENT GOING OUT OF HOSPITAL FOR INVESTIGATIONS

At times, an admitted patient is required to go out of the hospital for some advanced investigations, which are not available in the hospital where she/he is admitted. It may not be always possible and practical to discharge the patient and readmit him/her for the said purpose.

The treating doctor should explain to the patient the necessity of such investigation or procedure, its benefits, risks, complications, advantages, alternatives and cost involved. When a patient is being referred to outside hospital or diagnostic center by the admitting hospital, because of nonavailability of the facility for that investigation or procedure in the admitting hospital, then such admitting hospital should inform the patient accordingly, in writing and obtain his consent for the said arrangement. (Consent is only for his willingness to accept this proposal of admitting hospital—to go to outside center for investigation or procedure, and not for consenting for the risks involved in the procedure).

The admitting hospital should satisfy itself that the center where the patient is being taken to for the said investigations or procedure is well equipped with duly and suitably qualified staff and complies with all the statutory requirements.

The admitting hospital should arrange for a safe transport of the patient to and from the place of investigation or procedure. Patient should be shifted in ambulance accompanied by a nurse and doctor. Ambulance should be well equipped with all necessary medicines and equipment that may be required for the patient during transport.

Before shifting the patient to such an outside center, the condition of the patient, his vitals, etc. should be recorded in the Indoor Case Papers (ICP). The nature and purpose of the investigation or procedure should be documented in the patient's record. A referral letter, duly completed in all respect, should be provided to the doctors at referral center.

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The doctors at such outside center should obtain an independent and voluntary informed consent of the patient to undergo the said procedure or investigation, after satisfying all queries regarding the risks and complications, benefits and advantages and alternatives, etc. Such informed consent should be obtained by the doctors at that outside center.

After returning from such outside center, the condition of the patient and vitals, etc. should be again recorded in the ICP.

In case of any request from the patient to go out of the hospital for some other personal reason, e.g. for bank transactions or to attend a meeting or to cast a vote, etc. if in doctor's opinion the patient is stable, then she/he should be discharged and if she/he returns, then readmitted. If the doctor is of the opinion that the patient is not in a condition to go out of the hospital, she/he should not be allowed to go. In case the patient insists, the doctor should discharge him against medical advice and an "informed refusal" to continue to treat should be obtained.

"LOCUM TENENS" (LOCUM)

The Primary Consultant is solely responsible for care of the patients admitted under him. If such primary consultant wishes to go on leave for a few days during the period of admission of a patient under his care, then the primary consultant has to:

- Identify a locum who is equivalent in qualification and experience
- Seek the acceptance of the locum in writing that she/he will be taking all the due medical care of the patients admitted under care of the consultant proceeding on leave. On such acceptance by the locum, both the consultants should discuss and decide about the plan of care for the patient. Such plan of care should be documented and signed by both the consultants. The plan of care should have a clause to the effect that in case the locum doctor, while the patient is under his care, feels it necessary to deviate from the plan of care so agreed upon, due to change in the condition of the patient, may modify the same in good faith and for the benefit of the patient.
- The locum doctor should obtain informed consent of the patient in writing after conveying him the alternative arrangement made for his medical care and that she/he (the locum) will be attending to his medical needs.
- Transfer the responsibility of the patient to the locum temporarily (that is during the period of his absence).

The locum doctor in this case can take decisions regarding patient care, independent of the primary consultant. Such locum shall be solely responsible for any acts or omissions on his part, while treating the patient.

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On returning, the primary consultant takes over the patient management and continues to be responsible for the patient for the rest of the admission.

If the primary consultant wishes to go on a long leave throughout the period of admission of the patient then the primary consultant may, after obtaining a due informed consent from the patient, transfer the patient under care of another suitably qualified consultant.

It will be the discretion of the patient, after discharge whether to continue treatment with the primary consultant or the locum consultant.

If the patient refuses to be treated by the locum doctor, the primary consultant may discharge the patient.

FRAIL ELDERLY PATIENTS

All adults are capable to consent for their treatment. All adults, even if physically weak and frail should not be considered as incapable of consenting to their treatment. Physical weakness does not indicate patient's lack of mental capacity. In physically frail elderly adult patients with capacity:

- Patient's consent must be obtained before commencing any treatment.
- The time, place and environment for consent discussions should be suitable to the patient.
- It should be ensured that the consent provided by the patient is free and voluntary and is without coercion and not under influence of any other person/s.
- The information is provided to the patient in a format that he understands so as to make informed decision about his treatment.
- Doctor should especially ensure that the understanding of information provided by him to the patient is not hampered by hearing loss of visual impairment.

INTIMATE EXAMINATION

- There is no standard definition of an "intimate examination". Generally, examination of breasts, genitalia and rectum constitutes intimate examinations. However, any examination requiring removal of clothes or requiring touching a patient or requiring being in close proximity to the patient may constitute an intimate examination. Patient's views and beliefs will influence it.
- Doctors should know that intimate examinations are embarrassing or distressing to the patient. So, all efforts to maintain patient's dignity should be taken.
- Before proceeding for an intimate examination, a doctor must explain to the patient the nature of examination, its necessity and possibility of any pain or discomfort.

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INFORMED CONSENT IN MEDICAL PRACTICE

Principles and Conventions

Salient Features

- Exclusively devoted to the issue of consent in medical practice. Comprehensive information about the evolution of the concept of consent based on some landmark court judgments across the globe has been discussed.
- Keeping in mind the practical problems faced by the medical practitioners, templates of some kinds of consent and relevant information about consents in specific situations have been provided.
- A separate part is devoted to consents in medicolegal matters.
- This book will prove to be of immense importance to the students of medicine and those of other health sciences, medical practitioners and consultants, practitioners of law, and law officers of various courts, commissions and tribunals.



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