Consent in medical practice

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The competent adult patient has a fundamental right to give or withhold consent to examination, investigation or treatment. This right is founded on the moral principle of respect of autonomy.

The word "consent" is defined in the Oxford English dictionary as "permission for something to happen or agreement to do something" [1]. Consent is a concept of great complexity. For most people it means an agreement to a course of action based on full information, free of constraint and given verbally or in writing. In the field of Medicine, consent has always been a difficult and worrying area for medical officers.

Consent in medical practice need to be considered in the following situations.

- Examination of a living patient for the purpose of diagnosis and subsequent treatment (includes surgical procedures).
- Examination of a living patient for medico-legal purposes.
- Postmortem examination and removal of tissues for transplantation.
- Collecting data from patients for medical research purposes.

The nature of the consent

One of the important basic human rights is freedom from physical interference by another person. Therefore, a person with sufficient maturity and sound mentality can take a decision to accept or refuse the proposed physical examination, procedure or treatment by the doctor. With few exceptions, consent to examination and treatment is mandatory before a doctor approaches the patient. Any medical examination, investigation or treatment (or even deliberately touching the patient) carried out without consent may amount to an assault and could result in criminal proceedings as well as proceedings in the civil courts. This has been described in the Section 341 and 342 of the Penal Code of Sri Lanka [2].

Consent may be either implied or expressed.

Implied consent – This is determined by the behaviour of the patient and by far the most common form of consent in both hospital practice and general practice. Implied consent could be assumed when a patient calls a doctor to attend at home or attends the doctor's clinic for treatment. However, this is valid only for inspection, palpation, percussion and auscultation and not for more complex procedures.

Expressed consent – Anything other than that described in implied consent belongs to expressed consent. This may be either verbal or written. For majority of minor procedures and examinations verbal consent is sufficient but this should be obtained in the presence of disinterested third person. When obtaining verbal consent is witnessed, it is equally valid as written consent. Written consent is obtained in a properly prepared consent form for all major diagnostic procedures, anaesthesia and surgical procedures. The written consent should be for one specific procedure. Common practice of obtaining uninformed, unexplained "blanket" consent on admission to cover any subsequent medical procedure has no legal validity.

Informed consent – This concept has come to practice in recent years and many civil cases have been brought by patients stating that they did not understand the nature of medical procedure for which they gave consent. This concept is applied more strictly in the USA and Canada [3].

For the informed consent the following points should be noted:

- All relevant information about the disease or the condition from which patient is a suffering and treatment options must be outlined.
- Significant risks associated with every medical procedure and treatment must be disclosed.
- The patient must be informed about all the available alternative treatment options.
- Everything that is told to the patient must be explained in simple language with comprehensible non-medical terms.
- Every effort should be made to ensure that the patient truly understands what is being told.

From whom consent is obtained?

A valid consent can be given by conscious mentally sound adults. For this purpose, adult means persons over 18 years of age. In the case of sterilization or termination of pregnancy, the wishes of the spouse are usually sought but legally not necessary. When the age is below 18 years the consent should be obtained from *in loco parentis* – natural or adaptive parents, guardian or legal custodian. Obtaining a truly voluntary and properly informed consent from those who are mentally ill is a complex issue.

Even though patients may be mentally very abnormal in one respect they may be perfectly rational in other ways. However, a handicapped person may understand and be legally competent to give valid consent when explanations are simple, repeated and given to them by someone they trust. When the patient is unable to understand the nature of the illness and the proposed treatment the legal situation is unclear as no one can give consent on behalf of a mentally ill patient. However, in common practice doctor seeks consent from a relative or guardian.

Genuine emergencies are the exceptions to the general rule. The doctor may have to treat the patient, as the immediate treatment is necessary to save the life of the patient. However, the doctor must take utmost care to practice standards of care required consistent with the circumstances of the case. The doctor should try to obtain the consent from the next of kin or relative in such an emergency.

Validity of the consent

In general, the following five elements of the consent are mandatory for the consent to be valid [4].

- The consent must be given freely.
- It should be specific.
- It should cover the treatment and/or procedure to be done.
- It should be based on a proper understanding of the nature, implications and the complications of the proposed procedure.
- It should be given by person who is legally able to give the consent.

According to the Section 83 of the Penal Code of Sri Lanka, consent is invalid when given under fear, by misconception of facts or under intoxication [1]. Consent is invalid if the person giving consent is unable to understand the nature and consequences, of unsound mind or under the age of 18.

Alterations, hidden extras and restrictions

The consent should be obtained in a properly prepared consent form. Alterations should not be made to the consent form after the patient has signed it. If there is any change of the planned procedure or treatment, it should be informed to the patient and fresh consent should be obtained. Any additional procedures should not be carried out without the consent of the patient unless the additional procedure or treatment is really necessary to save the life of the patient [5].

Examination for medico-legal purposes

Medico-legal examinations are frequently carried out for the benefit of the patient and in some cases for diagnostic purposes and

treatment. Other than in a limited range of exceptions, expressed written consent must be obtained in every case. Third party (especially the police) cannot authorize examination without the consent of the patient or the victim. The person accused or otherwise has the right to be examined by a doctor of his own (not practiced in Sri Lanka). Also the patient or the victim has the right to refuse the examination by the doctor [3].

Consent for taking intimate samples – Intimate samples (blood, semen, tissue fluids, urine, saliva, pubic hair or swabs from body orifices) may be taken in certain circumstances from the people in the custody. The written consent must be taken unless the order was issued from the court of law.

Postmortem examination and removal of tissues for transplantation

Either a magistrate or an Inquirer in to Sudden Death (ISD) authorizes a judicial autopsy. The consent from relatives of the deceased is not necessary for a judicial autopsy. However, expressed written consent of the next of kin or relative is mandatory for a pathological or "academic" autopsy.

Consent for transplantation – The internal organs can be removed from a dead body for transplant purposes if the deceased person has indicated his willingness to do so when alive or when the written consent is given by surviving spouse or next of kin of the deceased [6]. The magistrate or ISD cannot give consent for the removal of tissues.

In the case of living donors, a full explanation of the procedure involved must be given to the donor; the possible consequences and risks must be fully explained. A written expressed consent should be obtained from the donor.

Consent in medical research

Research is an important aspect in medical practice**.** All the researchers who undertake clinical research must comply with the international ethical principles, which govern clinical research. Informed consent is an essential element in a medical research involving human subjects. Informed consent is a process by which a subject voluntarily confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent consists of three elements.

- Disclosure of information to the research subject.
- Understanding by the subject.
- Voluntariness of the decision.

Key points

- Consent should not be obtained under duress and must be fully informed.
- Verbal consent is perfectly valid in law but written consent is more important for major procedures.
- Consent should be obtained before the proposed procedure or treatment.
- Consent should be obtained only by someone who is appropriately qualified and familiar with all the details and risks of the proposed procedure or treatment.

References

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