

Consent in Paediatrics

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Abstract

Consent means voluntary agreement, compliance or permission. Consent signifies acceptance by a person of the consequences of an act that is being carried out. Informed consent is a communication process of providing the patient/parents/guardians with relevant information regarding the treatment and the diagnosis, so that they can make informed decisions. The process of informed consent in pediatric patients is not well understood. The amount of information to be disclosed in an informed consent is a matter of debate.

Keywords: Consent; Assent; Child; India; Informed Consent; Parents.

Introduction

Informed consent is a communication process that is ethically required before initiation of any treatment or procedure. It provides relevant information regarding the diagnosis and treatment needs so that an educated decision can be made. This is required for all aspects of medical care including preventive, diagnostic and therapeutic measures, and research. Consent is considered valid or real when it is given voluntarily without coercion, given by person with capacity and competence to give consent and has minimum level of adequate information about the nature of procedure to which he/she is consenting [1].¹

Reasons for Obtaining Consent

It respects the autonomy of the individual and protects the patient from any form of physical or psychological harm. It is also considered a legal document to protect the practitioner from claims associated with miscommunication [2].

Types of Consent

Expressed (specifically stated by the patient) Oral: Oral consent should be taken in the presence of uninterested third party. Mainly in cases where intimate examination of female is required. Tests necessitating removal of body fluids, radiological examination can be done after securing oral consent. Written: It is advisable to take written consent in the presence of disinterested third party (this third party is only to attest the signature of the patient). Written consent is mandatory in every invasive diagnostic/therapeutic procedures or any medico legal examination [3].

Components of Consent

An informed consent can be either general or specific. A general consent for treatment is obtained for physical examination, basic investigations and prescription of standard medications. Procedures and treatment considered a part of routine medical work up like administration of drugs or routine X- ray or blood investigations and intravenous cannulation do not require written consent [4].

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Informed Consent Guidelines for Immunization

Purpose: To guide immunization providers in developing their own policies and procedures regarding informed consent for immunizations, To ensure all are informed before receiving immunization. This information should include that all immunizations are voluntary. It is the ethical and legal responsibility of the immunization provider to obtain the informed consent. The need to obtain informed consent prior to an immunization is based on the principle that a client is autonomous and has the right to determine what happens or does not happen to them. Information, comprehension and willingness to participate (voluntariness) are fundamental elements of the informed consent document. The consent should adequately convey all the information needed for the subject to understand the immunization event, in addition to being in a language understandable to the client. A client's consent to participate must be free from coercion. Above all, the client should be able to understand the information presented in order to make an informed decision [5].

Who can Give Consent

As per Indian Majority Act, Guardian and Wards Act, and Indian Contract Act majority is achieved at an age of 18 years and considered a legal age for giving a valid consent for treatment. A child below 12 years (minor) cannot give consent, and parents/guardian can consent for their medical/surgical procedure. A child between 12-18 years can give consent only for medical examination but not for any procedure. Orphans or unknown or street children, the court is appointed as a guardian and any procedures/treatment requires court permission. In case of emergency, when parents/guardians are not available to consent, a person in charge of the child like principal or school teacher can consent for medical treatment (*Loco parentis*). A legal age of 18 years has been set to consent for termination of pregnancy (MTP Act 1971) and for Donation of blood and donation of organs (Transplantation of Human Organ Act 1994) [5].

Who should Obtain the Consent

The physician rendering the care may obtain the consent himself. Staff nurses or other health care providers are not entitled to obtain the consent although they can bridge the communication gap between the physician and the patient [6].

Elements of Informed Consent

It must be written in patient's understandable language & must not include too many medical terminologies. It should explain the nature of the ailment/ disease & its available treatment modalities including alternative treatment options. It should explain nature of the proposed procedure, its inherent risk, sequelae and potential benefits and prognosis of the patient with and without the proposed treatment. It must identify the attending physicians/unit in-charge/ hospital name & address. It must mention the date/time/place and number of witnesses. An acknowledgment that no guarantee and promises has been made to the parents concerning the result of any procedure. Assessment of parental understanding of the information that has been provided and that their queries have been answered to their satisfaction. Assurance that parents have the freedom to choose among the medical alternatives without manipulation. It must be comprehensive and readable with short and simple sentences [7].

Legal Implications of Informed Consent

Treating a patient without consent constitutes a battery, and failure of adequate disclosure amounts to negligence. Framework under which patient can obtain redressal for their injuries resulting from consent include criminal penal code (IPC-Indian Penal Code), Medical Council Act, and Consumer Protection Act (COPRA) [8].

As per the Indian Contract Act, if one party to the contract is misled or has entered into it in a different sense to that in which it ought to have been understood, then it would not be construed as a valid contract. Under the Indian Penal Code (IPC) 1860, Section 89 stipulates that an act done in good faith for benefit of a person under 12 years of age by consent, either express or implied, by the guardian or other person having lawful charge is not an offence by reason of any harm. This exception is not available if there is an intention to cause death or grievous hurt. In emergency situations, where there are no guardians/parents from whom it is possible to obtain consent, one can proceed to save the life of the child (Section 92 IPC) [8].

Medical Council of India (MCI) considers failure to obtain consent (from the parents/guardian in case of minors) prior to surgical treatment as misconduct. If the practitioner is found guilty, the Council may award the punishment as necessary and may direct the removal of their name altogether/temporarily from the register [8].

COPRA has emerged as weapon against unlawful medical practices in India and happens to be only social forum for the patients who are subjected to unethical medical practices. A main drawback with COPRA is that it has no provision to punish people who file unnecessary and false cases against the doctors [8].

Definition of Terms Related to Informed Consent

Consent By Proxy: Informed permission given by the parents or legal guardian as an authority and a responsibility to safeguard the welfare and best interest of their issue [4,5].

Informed Assent: Child's agreement to medical procedures in circumstances where he or she is not legally authorized or lacks sufficient understanding for giving consent competently [5].

Implied Consent: When the parents bring their child to a physician for treatment of any ailment it implies that they are agreeing for their child to go through the medical examination in the general sense [5].

Expressed Consent: When a patient specifically grants the physician permission to undertake the diagnosis and treatment of a specific problem. It may be an oral or a signature/written consent [6].

Valid Informed Consent: Consent with emphasis on patient's understanding of the reasonable and irrational elements of his/her decision [6].

Rules of Consent: Oral consent should be obtained in the presence of a disinterested third party (nurse). In criminal cases, the victim cannot be examined without his/her consent. The child under 12 years of age and an insane person cannot give valid consent to suffer any harm (Section 89, IPC). Consent is not a defense in cases of professional negligence. A person above 18 yrs of age can give consent to suffer any harm if the act is not intended and not known to cause death or grievous hurt.(section 87 IPC) [9].

Dealing with Refusal to Consent: When the parents/guardian refuse to undergo the desired diagnostic procedure/treatment after a complete and comprehensive information has been provided, they should be informed in a discreet professional manner of consequences of refusal, failing which the physician can be held liable in the court of law. The conflict of 'best interest standards' for treatment of

the child versus 'rational parent standard' for the attitude of parents is matter of never ending debate [10].

In the absence of an emergency, it is generally agreed that parents have a right to refuse treatment. However, it remains unsettled as to what should a physician do when a part of medical treatment is refused. For example, if the parents refuse for a lumbar puncture in a child with suspected meningitis, but consent to all other blood investigations and treatment. No court of law can protect the physician from litigations if he denies treatment on such grounds [10].

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