REVIEW ARTICLE

Informed Consent in Pediatric Practice

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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. There are four basic elements to the content of informed consent form: nature of procedure, risks, benefits and alternatives. The article delineates the essential elements and legal implications of informed consent in pediatric practice.

Key words: *Assent, Child, India, Informed consent, Parents.*

Informed consent is a communication process that is ethically required before initiation of any treatment or procedure(1). 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 voluntary 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(2). Definitions of terms related to informed consent have been described in ***Box* I**.

The legal implications and ethics of consent related to practice involving children is complex and poorly understood. For example, do we need to tell every parent that your child can have a cardiac arrest after administration of phenytoin infusion? Will this actually help the doctor patient relationship? This review intends to provide information to improve the existing lacunae in the process of informed consent.

THE NEED FOR CONSENT

Ethical basis for an informed consent is that it respects the autonomy of the individual and protects the patient from any form of physical or psychological harm, thus ensuring active participation of the individuals in treatment intended to restore their health. It is also considered a legal document to protect the practitioner from claims associated with miscommunication.

COMPONENTS OF CONSENT

The essential components of consent includes voluntariness (willingness of patient to undergo treatment), capacity (patient is able to understand nature of treatment) and knowledge (sufficient information as to nature of treatment disclosed to the patient)(3).

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).

A 'specific consent' is required for any procedure or specific treatment involving a marginal risk to the patient including major diagnostic or therapeutic

BOX I DEFINITIONS 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
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
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
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.
Valid informed consent	Consent with emphasis on patient's understanding of the reasonanble and irrational elements of his/her decision.

procedure and prescription of a potentially toxic medication. 'Blanket consent' for all treatments/ procedures deemed essential by physician is unethical and is against the law(5).

The amount of information to be disclosed in an informed consent is a matter of debate. Delhi Medical Council defines 'adequate information' as information that would enable the patient to make a balance judgment to undergo the treatment or not(6). The basic elements to the content of informed consent form that may be addressed before initiation of any treatment or procedure: nature and need of procedure, risks, benefits, alternatives and consequences of refusal of treatment.

Types of risk include: common risk (risks which a patient with a common sense can understand), known risk (risks already known to the patient), remote risk (risks that are not reasonably foreseeable) and minor risk (risks that if they materialize will not cause patient any substantial harm/pain/discomfort). There might be risks which a physician might not consider it important to disclose however a reasonable patient/parent might attach importance; such risks are called 'material risk'.

Disclosure of material risk is mandatory in Canadian and United State laws(7). However, Delhi Medical Council considers no need to explain remote or theoretical risks involved with the procedure that might confuse the patient resulting in refusal to treatment(6). Elements of an informed consent form are summarized in ***Box* II**.

Who Can Give Consent?

A person who has capacity and competence can consent to his/her treatment. A person is said to have 'capacity' when he/she can understand the necessary information, retain that information, use it for decision making and communicate the decision by appropriate means(8). It also depends on what is being consented; more the risk of the treatment offered, greater the capacity required to understand and comprehend(9). Various tools and tests of competence to consent have been designed. MacArthur Competence Assessment Tool-Treatment (MacCAT-T) Scale assesses patient's competence in terms of: understanding the information, reasoning the risks/benefits of their choice, consequences of their choice and expression of their choice(10). The process of informed consent should be voluntary, without coercion.

There are fixed guidelines outlining the exact age of consent for medical or surgical treatment. In India, 'majority' is achieved at an age of 18 years and

BOX II: ELEMENTS OF AN 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.
- Nature of the proposed procedure, its inherent risk (the risk known to be an adverse effect by mere performance of that procedure), sequelae, and potential benefits.
- 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.
- Must be comprehensive and readable with short and simple sentences.
- A space must be left if some additional risks are particularly more in the concerned patient vis-à-vis other children.

considered a legal age for giving a valid consent for treatment as per Indian Majority Act, Guardian and Wards Act, and Indian Contract Act(11). A child below 12 years (minor) cannot give consent, and parents/guardian can consent for their medical/ surgical procedures(12). A child between 12-18 years can give consent only for medical examination but not for any procedure(13).

For children who are orphans or unknown or street children, the court is appointed as a guardian and any procedures/treatment requires court permission(14). 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*)(15). A legal age of 18 years has been set to consent for termination of pregnancy (MTP Act 1971), donation of blood and donation of organs (Transplantation of Human Organ Act 1994)(11).

Role of Assent in Pediatric Practice

Healthcare of older children and adolescents is complex as they are in the process of developing competence to participate in decision making on their health. A child's agreement to medical procedures in circumstances where he or she is not legally authorized or lacks sufficient understanding for giving consent competently is called 'assent'. Children are considered to "assent" when they have sufficient competence to understand the nature, risks, and benefits of a procedure, but not enough competence to give fully informed consent(16).

It is considered by age of seven years, a child develops competence to distinguish right from wrong and can assent to treatment/procedure. A child of age 7-14 years is capable of understanding the outcome of a procedure. However the age of seven has been challenged by a study that indicated that a

child of less than 9 years is not capable to assent(17). Child's assent primarily respects the autonomy and rationality of children on their medical care(18). It involves creating awareness on the nature of illness, explaining the nature and outcome of the treatment/ diagnosis offered, assessment of understanding and willingness to accept the proposed treatment(18).

Who Should Obtain the Consent?

Ideally, consent may be obtained by a person who is capable of communicating all the necessary information required to make a decision regarding their health care. The physician rendering the care may obtain the consent himself(19). It remains unclear whether a house surgeon/intern can obtain an informed consent(20). 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. In case where the patient is treated in a hospital, failure to obtain consent has implication on both the employee (doctor) and employer (hospital) [theory of *respondent superior*](21).

PERCEPTION OF INFORMED CONSENT IN SOCIETY

The process of informed consent is acknowledged by majority of parents as an essential step toward their child's, healthcare(22). Parents consider it a legal document to agreement of treatment/procedure and a document which would protect the physician against future litigations, rather than providing with relevant information about the procedure(23).Majority of patients in a study felt the informed consent form was meant to remove the responsibility of the doctor in case of untoward incident(24). 90% of patients had filled the form in fear, anxiety and insecurity(24). Parents at the time of consent are distressed with seriousness of their child mixed with a sense of responsibility towards the child, making them vulnerable to consent(25).

The gap between parents and the physician results from lack of effective communication skills, empathy, time and patience, and ignorance about the risks and side effects among the physicians. This emerges from the lack of training in medical ethics in undergraduate and postgraduate curriculum(26). In a survey conducted on attitude of doctors towards medical ethics, it was observed that only one third of the respondents had knowledge of code of medical ethics(27).

The information conveyed to the parents would depend upon the intelligence of the parents, educational status, religious/cultural/beliefs, and family/peer pressures. Majority of the parents in a study did not understand the nature of treatment/ procedure(28). In another study, parents preferred the decision to be left to the physician(29). It has been observed that older, less educated and poor patients have lesser recall of information provided to them while consenting to treatment(30). This study also outlined the fact that Indian patients can understand the treatment options, if explained properly and the excuse that the patient was illiterate and could not understand the process being explained is unethical(30).

Poor patients from the lower socio-economic strata seeking medical treatment in public hospitals in India face a unsatisfactory medical environment in the form of non-availability of beds, lack of quality care, and lack of opportunity to interact with health professionals, doctor. The resident doctors working in such hospitals have to work with limited resources and infrastructure, lack of time, and prolonged working hours. How many doctors are able to obtain a proper informed consent before initiation of treatment in such a medical framework remains to be elucidated.

Private centers, on the other hand, rely on effective communication with the patient regarding the diagnosis and possible outcome of treatment, due to lesser patient load and more resources. Does that mean that private doctors take a proper, valid, informed consent? To the best of our knowledge, there are no Indian studies which outline the difference in the valid consents taken at government and private hospitals. However, it is clear that the law applies equally to both of them.

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

treatment administered in absence of informed consent include criminal penal code (IPC-Indian Penal Code), Medical Council Act, and Consumer Protection Act (COPRA). 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(12). 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)(12).

Medical Council of India (MCI) considers failure to obtain consent (from the parents/guardian in case of minors) prior to surgical treatment as "misconduct". The code of misconduct can render him/her liable for disciplinary action. If the practioner is found guilty, the Council may award the punishment as necessary and may direct the removal of their name altogether/temporarily from the register, and this is widely publicized in local press and in the publications of different medical association/society/bodies. Main flaw with the clause concerning consent for medical procedure and treatment is that, there is no provision for patients to approach the council directly or for claiming any compen-sation(31).

Of the existing approaches, the most cost-effective, patient friendly forum is through the COPRA, which aims to settle the consumer's dispute in a fast and cheap way(32). 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. Hence, a screening committee was suggested to screen the cases that need to be heard in the forum. Another disadvantage of the forum is that it does not consist of any medical professional in the panel. Doctors who are working in a hospital that is rendering absolutely free of cost treatment for their patients are excluded from the Act(33).

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(34).

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. However, in children with life threatening illness or other serious or chronic medical condition, informed refusal can amount to 'medical neglect', which is included as a form of child maltreatment or child abuse in USA(35). However, Indian laws are silent on this aspect (36). Informed refusal must be dealt by the physician with persuasion, education and removal of obstacles to expression of underlying values. Court intervention may be sought when parents refuse treatment, which the health care professionals deem essential; however, post treatment rehabilitation needs to be offered to improve parent-child relationship(37).

IMPROVING THE PROCESS OF INFORMED CONSENT?

Books/illustrations/videos: The contents of consent form can be augmented with audio-visual interventions like booklets/illustrations/video clips(38). However, a recent Cochrane review on role of audio visual interventions in clinical trial participation revealed that there is no conclusive evidence that it improves the patient's understanding /knowledge, at least in the long term(39).

Communication/oral disclosure: Parents expect the treating physician to speak in a honest, clear, unambiguous manner with clarity of information and at same time giving plenty of space and opportunity to answer their questions(40). It may be prudent to record the nature and content of the conversation with the parents and their response in the medical record with time and date. Understanding of the ailment and desired outcome may be ensured before the parents place a signature in the consent form.

Making consent forms simple: A consent form in developed nations is expected to be readable by 8th grade level, but there are no guidelines developed in India(38). It was observed that the consent form given to the parents often has plenty of tough medical terminology and often is not legible and scribbled in a poor handwriting(26,41). The consent forms need to be comprehensible and written/typed legibly. It would be advisable to use short sentences with simple vocabulary and use of non-medical terminology as far as possible. The consent forms written in patient's own language might improve the comprehension and understanding(42). In cases where the same language is not possible, a good interpreter should be provided. The consent form should be signed by all parties concerned (parents/ guardian/doctor/witness) to make it a valid document(43).

Third person witness: There is no conclusive judgment mandating a witness by a uninterested third person while consenting to medical treatment. However, it is realized that importance of third person witness improves, especially when the consenting parents are illiterate and have consented by placing a thumb impression(43).

Anticipatory guidance: Nursing staff that has been trained in a particular specialty can educate, empathize and prepare the parents before the anticipated formal meeting of physician and parents. This may improve the communication between the physician and parents and remove the fears and barrier pertaining to the desired procedure/treatment(44).

Informed consent as process: Obtaining an informed consent must be considered a process rather than a point which ends once the patient signs the consent forms. It is a continuous two way communication and must proceed as frequently as possible during the entire treatment of the patient. It may also be accomplished by giving a copy of consent form to the parents so that they can read them carefully at home and might clarify any further queries in the next visit. It was observed that problems in competence and understanding reduced markedly in the post signature phase when further discussion took place(22). In a study evaluating the process of informed consent in pediatric oncology patients, it was observed that about 90% of the parents felt the need for a written booklet(24).

Waiver of consent: An attitude of the parents/ guardian, where they wish not to have information that might unduly distress them, and leave the decision on the physician must be honored and this is called 'waiver of consent'. Indian patients who are poor, underprivileged, with low education levels have blind faith in the doctors and believe the best of treatment will be offered to their child. Such waiver of consent should be documented in medical records, and preferably should be in the form of signed proforma.

It is the physician's responsibility to decide for the need of the proposed investigation or treatment and to explain the parents about it. Four basic elements of an informed consent should include the nature of the procedure, the risks, the benefits, and the available alternative treatments. As the doctrine is of recent origin, guidelines have yet not been developed by the court and are evolving slowly. Explicit standards that delineate specifically which procedures require consent may be required to assure more uniform practices. Therefore, each institute/centre must make its own written consent form for common procedures and treatment.

Contributors: JK and NA: Literature searches, writing of the manuscript. MN: conceptualized the idea and approved the final version. JK would act as the guarantor.

Funding: None.

Competing interest: None stated.

KEY MESSAGES

- Best interests of the child must be borne to assess potential harms, benefits while making decisions.
- An informed permission of parents is essential for an informed consent.
- Assent of child must be taken when possible.
- A copy of the consent form should be given to the parents.

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