

Dialysis consents

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CONSENT

Definition

Consent means “ **Willingness of a party to undergo examination/procedure/treatment** by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal.

In law, It means active acquiesces or silent compliance by person legally capable of consenting. **In India , Legal age of consenting is 18 .**

YES

INFORMED CONSENT?

NO



IMPORTANT REQUIREMENT

- The consent shall have the **name of the doctor** performing the procedure.
- The consent form shall at a minimum be **bilingual**. If consent is taken in a different language, there should be clear **documentation** detailing the language in which the patient has been counselled and if any interpreter has been used.
- It should have **the risks, benefits and alternatives** of the procedure as a part of the documentation.
- The person performing shall be responsible for the entire consent process including providing explanation and taking the signature.

IMPORTANT REQUIREMENT cont..

Informed consent process adheres to statutory norms

- The consent shall be documented before the procedure
- There should be at least **one witness signing** the consent form. The witness shall be a person who was present for the entire duration of the communication between the doctor and the patient.
- In case the patient has to undergo a procedure repeatedly for a long time (e.g. dialysis) an informed consent is taken at the first instance and shall have a defined validity period, but not more than 6 months. **(PRE 4b- NABH 5th Edition)**
- The patient endorses the consent at each repeat treatment. However if there is a change in the treatment modality / addition of another modality then fresh consent shall be obtained

IMPORTANT REQUIREMENT cont..

- The consent shall be taken from the patient above the legal age (**Above 18 year**) for giving consent. **No one can consent on behalf of a competent adult.**
- There should be a **documented policy , who can give consent(next of kin/legal guardian)** if the patient is incapable of independent decision making. **The order of preference of next of kin/legal guardian is spouse, son/daughter/parents/brothers/sister.**
- **In case of life threatening situations when a patient is incapable and next of kin is not available, in the interest of the patient, the treating doctor and another clinician can take a decision to safeguard the patient's life.**
- A doctor member of the team can take consent on behalf of the person performing the procedure.



**It is no longer an option.
It is now a must under the
current guidelines &
regulations**

As per QAI Standards for dialysis centres

- **PRE.5:** The center documents a procedure to obtain informed consent.
- **Criterion a.** Documented procedure incorporates the **list of situations** where informed consent is required and adheres to applicable statutory norms.
- **b. Informed consent** includes information regarding the procedure, its **risks, benefits, possible complication, alternatives** and as to who will perform the procedure in a language that they can understand.
- **c.** The procedure describes who can give consent when patient is incapable of independent decision making.
- **d.** Informed consent is taken by the person performing the procedure.

Staff is trained on respecting patient's preferences and choices, informing about their options for care and treatment, and obtaining informed consent.

Formulate Policy

- The Consent Policy will include all the guidelines and doctors should familiarize themselves with guidance relevant to their area of practice.

METHOD

THE PATIENT'S RIGHTS

- Patients must be **given information, in a way that they can understand**, to enable them to exercise their right to make informed decisions about their care.
- **Right to give or withhold consent** prior to examination or treatment.
- Allowed to decide whether they will agree to the treatment
- May refuse treatment or withdraw consent at any time.
- **Minors and incompetent adult's** rights regarding informed consent **will be exercised through their parents or legal representative.**
- The **physician performing a medical or surgical procedure** on a patient is **responsible for obtaining the patient's informed consent** prior to the treatment or procedure

DOCUMENTATION

- If preoperative/ pre procedure medication (sedation or pain medication) is to be administered, **informed consent or verification of informed consent must be obtained prior to the administration of such medication.**
- The physician must document in the medical record, on an approved hospital form when available, consent for all therapeutic and diagnostic procedures where disclosure of significant medical information, including significant and frequently occurring risks involved.
- He would assist a patient in making an informed decision whether to undergo the proposed treatment or procedure. Such procedures include surgical and other invasive procedures, other treatments with significant risks, and transfusion of blood and/or blood products.
- The approved hospital forms must always be completed in all cases; involving a procedure for which documented consent is required.

Validity of Consent

DURATION OF INFORMED CONSENT

- **Continuing force and effect** until the patient revokes the consent, or until circumstances change so as to materially affect the nature of, or the risks or benefits of, the procedure and/or the alternatives to the procedure to which the patient consented.
- For example:
 - ✓ if a patient has been admitted for a specific treatment or procedure, the consent should be valid through the course of the admission unless the patient's condition or treatment changes significantly.
 - ✓ In that event, the physician should obtain a new informed consent. Generally, informed consent should be obtained and documented no longer than 60 days prior to a procedure, surgery, or treatment. After this time period, the informed consent should be re obtained and re documented by the physician.
- **Revocation** - A patient may revoke consent verbally or in writing. This should be communicated to the patient's physician and documented in the medical record.

Components of consent

The Written Consent Form Must include as a minimum:

- The **name(s) of RMO's/ attending doctors** immediately responsible for the performance, and/ or the supervision of the treatment or procedure, resident physician and the attending doctors.
- A **brief description** of the recommended treatment or procedure.
- A statement that relevant aspects of the **treatment, or procedure, including indications, benefits, risks, and alternatives** including no treatment have been discussed with the patient in language that the patient could understand.
- A statement that the patient had an opportunity to ask questions.
- The **Date and Time** the discussion took place and whether the patient consented to the treatment or procedure.
- The **written signature of the practitioner** writing the note (including the Practitioner's legibly written name).
- **Signature/Thumb impression of Patient/Key Attendant/Guardian** as applicable and legible written name.

Components of consent cont...

- **Obtaining Consent**:-Successful relationship between doctors and patient depends on trust.
- The Physician must respect the patients autonomy, their **right to decide** whether or not to undergo any medical intervention.
- Patients must be given sufficient information in a way they can understand to enable them to exercise their right to make informed decision about their treatment.
- The Physician must give patients details before he/she decides to consent to an investigation or a treatment.
- The Physician must give **details of the diagnosis and prognosis of the disease**, if left untreated.

One can only take adequate precaution and act with care and diligence. Maintaining good relationship with patient often works better than the best informed consent!





“One cannot know with certainty whether a consent is valid until a lawsuit has been filed and resolved.”

