**TITLE** : INFORMED CONSENT **:** NECESSITY IN TRANSFUSION MEDICINE

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**INFORMED CONSENT : A NECESSITY IN TRANSFUSION MEDICINE**

**Abstract**

Informed consent in transfusion medicine has been slowly gaining importance in India, given the increasing awareness among the people about their rights with regards to their health and treatment options available for any kind of ill health. The medical practitioner and the blood banker in particular are more attuned to the legal hassles linked to transfusion activities and have come to the realization that informed consent is a fundamental tenet which at no cost be ignored. The process of blood donation itself per se requires active intervention and necessitates the informed voluntary consent of the blood donor.In this context, the blood donor has to be very well made aware of all the aspects of blood donation prior to the donation process At the recipients end , it will amount to battery if transfusion is done without valid informed consent of the patient who is the recipient. Among growing concerns about the rational and judicious use of blood and blood components and the fact that no unit of blood/blood components can be said to be hundred percent safe, the role of informed consent cannot be underestimated.

Keywords : blood transfusion, informed consent

**Introduction**

The doctrine of informed consent has been promoted by American association of Blood Banks since 1986[1] A long and contentious history exists for the practice of taking informed consent of the patient before any medical or surgical intervention, and has reached a matter of utmost significance among the medical fraternity, the patients, the lawyers and the general public. At one end of the spectrum are the voluntary blood donors who should be made aware of the benefits and risks of blood donation and also instilled with the confidence that their privacy will not be violated. At the other end of the spectrum are the recipients of the transfusion ,the patients who should know about the inherent advantages and adverse effects associated with the transfusion. More crucial decision making for the patient concerns the transfusion transmissible infections and most importantly about the window period of the disease states when even the most sensitive tests cannot detect the infection and thus the realization of the fact that there is always a risk of transmission of infection.

Article 21 of the Indian Constitution guarantees protection of life and personal liberty to every citizen. The Supreme Court of India has held that the right to live with human dignity enshrined in Article 21 of the constitution derives from Directive principles of state policy and therefore includes protection of health and transfusion services are essential to treat many health conditions.

Blood has been classified as a drug under Indian Pharmacopoeia and thus a commodity which brings the blood transfusion services under the ambit of consumer protection act 1986 and the latest bill 2018.

The above aspects add to the legal implications associated both with blood donation and transfusion and further highlights the necessity of obtaining valid consents from both the donor before donation and the recipient before transfusion as has been emphasized in the International society of blood transfusion, s Code of Ethics.[2]

**What is informed consent?**

Components of an informed consent are

i. The donor/patient should possess the capacity to give consent

ii. The consent should be specific to the procedure and there should be complete disclosure of the nature of procedure, the associated advantages and risks and choice of alternative procedures if any.

However a doctors nondisclosure will be excused in case of patients under the therapeutic privilege if disclosure would interfere with the treatment ,upset the patient or adversely affect the patient.

iii. The donor/patient should comprehend the details and give the consent voluntarily without any force or duress.

In transfusion medicine there is no role for implied consent ,it has to be expressed and written.

**Informed consent of the blood donor**

Blood donation is a voluntary act without any form of coercion or remuneration. Prior to donation the blood donor needs to be explained in clear terms and in a language he understands the whole procedure for blood donation and the various benefits and the attendant adverse effects of the donation process in an atmosphere which is comfortable to the donor.

The level of comprehension by the donor may be strengthened by repetition of relevant information in multiple formats [3] Pre donation counseling regarding the mandatory serological tests currently being performed in India on each unit of blood collected is a absolute necessity as screening for HIV is also involved. Assurance of maintenance of confidentiality of the donor is of paramount importance.[4]The donor is provided a donor questionnaire in the language known to him with the attached informed consent form which he has to fill and sign after due perusal. Confidential unit exclusion is a choice which has to be given to all the donors as per WHO guidelines.[5]

The donors permission is also sought for fractionation of plasma prepared from the blood unit collected from him into blood products. Recent guidelines from National blood Transfusion council requires the donors consent for using the blood and components collected from him in other blood centres if need be.

The willingness of the donor to either know about the results of the screening tests or the right to deny access to any such information is the donors prerogative. The later scenario leads to an ethical dilemma to the blood banker as it poses a threat to society at large and donors family in particular with regard to transmission of infection. Thus informed consent has a crucial impact on liability in voluntary blood donors.[6]

**Informed consent of the patient**

Any invasive therapeutic procedure without the consent of the recipient is considered a battery [Section 350 IPC] Blood transfusions which may be liberal or restrictive[7]are categorized under invasive procedures and necessitate the informed consent of the patient which can be stated to be a protective tool for the clinician.

The principle of informed consent arises from the idea that every sound minded individual has a right of personal autonomy to decide what should be done with his/her own body.[8]A separate valid informed consent for blood transfusion which should not be clubbed with any other invasive procedure and hence not a blanket consent, is very much essential[9] and gains significance on three accounts.

The first aspect being that the transfusion procedure of blood/components can be associated with mild to severe and sometimes life threatening transfusion reactions.

The second and also one of the more serious consequences would be the transmission of transfusion transmissible infections which can occur if the donor happens to be in the window period of the disease or when improper testing is done as it happened in Tamil Nadu recently [10]when HIV reactive blood from a young male donor was transfused into a pregnant woman and she also became reactive .

The third aspect would be a clear case for medical negligence when there is mismatched blood transfusion and of course in such a case even a valid informed consent would be of no help.

With the above facts as a background it can be assumed that the process of getting the informed consent should not be reduced to a mere formality. Development of visual aids like a standardized video regarding the pros and cons of blood transfusion may be useful[11] in aiding the easy comprehension by the patient. The information should be provided to the patient in comfortable surroundings in an appropriate and timely manner[12] The patient should also be given the choice of alternate treatments if any. Witnessed consent with both the doctor and patient affixing their signatures would be foolproof[13]

**Duration of validity of informed consent**

It would be very unfair to task the patient with getting the consent for each transfusion when many are required.. The ideal solution would be to get an informed consent for an entire stay in the hospital as it is practiced in many countries. Some hospitals have a policy of having a consent valid for the entire year when the patient requires repeated blood transfusions at regular intervals.

**When informed consent is not possible**

Under Section 92 of the IPC,a registered medical practitioner gets legal immunity to proceed with the proper treatment even without the consent of the patient in an emergency[14], when the patient is incapable of understanding the nature of treatment and there are no legal guardians/ heirs to sign the consent.

**Informed consent when patient is a child**

In the event of patient being a child or minor the informed consent is usually given by the parent/guardian though there are no clear guidelines regarding informed consent in children. As per section 89 of the IPC when a child is under 12 years of age and cannot give valid consent, laws govern that consent can be taken from a person with parental responsibility.[15]

**Informed refusal- Grey area**

If the conscious patient who is fully in his senses refuses blood transfusion he should be given some time for rethinking and reconsideration of the decision[16] Jehovahs witnesses pose a big ethical dilemma to the clinician with their staunch religious beliefs regarding non acceptance of blood and blood components.[17]However the clinician can approach the court and get the sovereign power of Guardianship over persons under disability [Parens Patriae] and go ahead with the transfusion even though there is explicit refusal. In reality though it involves a lot of effort on the part of the clinician and he still can be held liable for breaches when he has ordered the transfusion in the face of an express refusal.[18]

**Legal Implications**

Many instances of litigations have arisen over lack of specific informed consent for blood transfusion and the medical profession has paid compensations to the litigants as per rulings of the grievance redressal systems like the courts and consumer redressal forums as in M.Chinnaiyan vs Sri Gokulam hospital hospital[19] and Harish Chadha vs Indraprastha Apollo hospitals[20]Most often the cases pertain to adverse transfusion reactions or due to transmission of transfusion transmissible diseases where the patients feel that they have not been disclosed the attendant risks and rarely if there are severe adverse donor reactions in case of donors . The courts may apply the prudent patient approach or prudent donor approach to decide whether the risk would have been considered significant by the reasonable patient /donor ,therefore requiring disclosure in making a decision. However one cannot know with certainty that a consent is valid until a lawsuit is filed and resolved [21]

**Conclusion**

Though International Society for blood transfusion, the National blood transfusion council , the Central Drug Standards control organization and other regulatory agencies have given guidelines for seeking the informed consent from donors and patients, the gravity of the consequences of lack of informed consent have still not been understood by many clinicians and blood bankers alike. With litigations becoming more common and with the public being more conscious of their rights, educating the medical fraternity regarding the significance of the informed consent is the need of the hour. Further it may be advisable to push for a legislation that lack of informed consent is a case for medical negligence.

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