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## Editorial

# Medicolegal, ethical, and regulatory outlook of Blood transfusion services

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Blood is considered a ‘drug’ as it is administered internally. It is taken under section 3(b) of the Drugs and Cosmetic Act (D and C Act), 1940 and Drugs and Cosmetics Rules, 1945, which were modified in 2020.<sup>1</sup> This Act and the Rules provides the legal framework for regulating the functioning of blood centres, which determine the quality of the blood transfusion services in India.<sup>2</sup> Blood transfusion services (BTS) ensure the availability and quality of blood, establishes donor management and storage provisions, tests for transfusion transmissible infection (TTI) and practices appropriate usage of blood. Blood transfusion is a cornerstone of modern clinical practice.<sup>3</sup> Blood or blood components should be ordered and administered safely and judiciously. Blood transfusion is not a single event but a process which begins with donor considerations (whether their donation is safe and whether it is safe for any patient to receive), infectious disease testing, compatibility testing, necessary modifications such as irradiation or leukocyte reduction if required and at the end safe transfusion in the patient.<sup>4</sup> The provision of blood and blood products from donation to transfusion must be based on good ethical principles and quality guidelines.

## 1. Framework of Indian Blood Transfusion Services

The BTS in India is under various authorities like CDSCO, and State Drug Controller/FDA having regulatory role and NACO, NBTC, SACS, and SBTC, having advisory and program implementation roles.<sup>5</sup> Drug controller is the regulatory authority. In 1993, licensing of blood centres was made mandatory by the Supreme Court of India. The license must be renewed every five years. Blood from voluntary blood donor can only be collected by a licensed blood centre; which can be either a licensed Government Blood Bank, or a licensed Regional Transfusion Centre. The procedure for licensing of blood centre is laid in the “Drugs and Cosmetics Act-1940” and “Drugs and Cosmetics Rules, 1945”. The drug controller inspection is preceded by an inspection by the State Blood Transfusion Council, the advisory body.<sup>6</sup>

NACO frame guidelines for Blood transfusion. The National Blood Policy is an offshoot of the National Aids Control Program.<sup>7</sup> NACO plays a pivotal role in infrastructure development, setting up component separation units, promoting voluntary blood donation and training of staff.<sup>8</sup>

### 1.1. National blood policy

The National Blood Policy (NBP) -2002 documented strategies for improving transfusion services. It also outlined methods for motivation and ethical clinical use of blood.

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Further, it is also attempted to eliminate profit making motive in blood centres.

National blood transfusion services: - In January 2014, the recovery of charges of processing the blood and blood components was approved and guidelines were set for uniform charges. It was suggested to revise it once in 3 years. In March 2014, financial assistance for conducting camps in outdoor locations and mobile blood donation vehicles with the objective of streamlining voluntary blood donation in NACO supported blood banks was notified.<sup>9</sup>

The national plasma policy, an addendum to the national blood policy was introduced in June 2014. It was to ensure adequate supply and access to high-quality human plasma-derived proteins for the clinical and therapeutic use. Its aim was to mobilize the excess plasma at blood centres for fractionation to meet the increasing demand for plasma products.<sup>10</sup>

Fundamental rights of the Constitution under Article 21 states that no person shall be deprived of his life. Blood transfusion can be lifesaving and can be fatal, therefore, comes under this section of fundamental rights. Besides under Section 269 of IPC, provisions for fine and imprisonment for negligent act likely to spread infectious disease its use can be dangerous to life.

## 2. Consumer Protection Act

In April 1992, The Supreme Court upheld the National Consumer Commission's judgement, whereby patients who received deficient services from medical professions and hospitals are entitled to claim damages under this Act. Blood transfusion services and both donor and recipient can take the cover of this Act.

## 3. Ethics in Blood Transfusion

The international society of blood transfusion (ISBT) instituted a code of ethics which are adopted by World Health Organisation (WHO) and can be divided into two sub categories: -

### 3.1. Related to blood centres

#### 3.1.1. Donors and donations

1. Donations shall be voluntary and nonremunerated with informed consent.
2. A profit motive should not be the basis for the establishment of a blood service.
3. The donor's health and safety must be protected
4. Anonymity between donor and recipient must be ensured
5. The donor should understand the risks to others of donating infected blood.
6. Donation must be based on regularly reviewed medical selection criteria only.

7. Blood must be collected under a suitably qualified, registered medical practitioner.
8. All matters related should follow internationally accepted standards.
9. Donors and recipients should be informed if they have been harmed.
10. Blood is a public resource and access should not be restricted.
11. Wastage should be avoided.

### 3.2. Related to hospitals: Patients

1. Patients should be informed of the known risks and benefits of blood transfusion and/or. alternative therapies and have the right to accept or refuse the procedure.
2. If the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.
3. Transfusion therapy must be given under responsibility of a R M P.
4. Genuine clinical need should be the only basis for transfusion therapy.
5. There should be no financial incentive to prescribe a blood transfusion.
6. Only those components be used that are appropriate and optimally safe.
7. Blood transfusion should follow this code of ethics.

## 4. Medico Legal Aspects

The two general principles that should take care of during blood donation are that there should be no harm to the health of the donor and no risk to health of the recipient. Consent, confidentiality and care of the donor are blood centre's obligations towards the donors. Although the lawsuits by donors are relatively rare, failure to consider any of these obligations may lead the blood centre to serious liability.

Although informed consent is a common law concept, it has also been incorporated into professional regulatory standards. According to American Association of Blood Banking (AABB), written consent of the donor is must before the donation. The procedure should be explained to the donor in their own language. The information to be provided to the donor may vary with the type of donation. For example applicable regulations require additional information regarding risks of a haemolytic reaction to be given in the case of plasmapheresis donors. Even if the informed consent is taken, the donor still retains the right to sue in case of negligence.

In case of deaths due to blood transfusion, the relatives of deceased may charge of medical negligence against doctor. If the patient survives, he/she may claim for damage. Management and investigation of serious adverse reaction is of utmost importance. Most of the medico-legal

problems faced by the doctors are due to the reason that medical records are not properly maintained and there is lack of informed written consent. Only proper and timely investigation of the case by the persons well conversant with such investigations can solve the crisis. For safe transfusion step by step procedure must be adopted which should include informed consent, immuno-hematological results, specific prescription about quality and quantity of blood product.<sup>11</sup> In an emergency procedure may be exempted but it should be documented. Facts related to transfusion must be recorded in the hospital file and this hospital file should be kept in safe custody for a particular period as per the laws.<sup>12</sup>

Blood should never be administered without the consent of the person. If the person has ever expressed consent against blood transfusion it should not be carried out as it may result in unfavourable court decisions.<sup>13</sup> Jehovah witnesses believe in not using the blood and blood products to save their lives even when it is indicated therapeutically. Blood transfusion against the religious beliefs is problem in emergency situations particularly when the victim is unconscious. In that case, informed consent from relatives should be taken before transfusion.<sup>14</sup>

Nursing officers should be trained in transfusion but doctor must be able to intervene quickly if needed.<sup>11</sup>

Investigation in case of blood transfusion reaction should be done without delay to reach a conclusion. First of all, check for clerical error at ward (at time of transfusion) and at blood centre (at time of grouping and cross matching and issuing of blood). Blood grouping from the bag and patient should be repeated to rule out any error in grouping. Regrouping is performed pretransfusion and post transfusion samples. Usually, ABO and Rh grouping and serum grouping is done. Re- cross matching is also performed on pre transfusion and post transfusion samples for IgM and IgG major and minor antibodies by saline, enzymes, and indirect agglutination test. Red cell antibody screening is also performed for pre and post transfusion samples.<sup>15</sup> Amount of unutilized blood in the bag is noted and examined with naked eye. Colour and special features of the blood in the bag/tubing of the bag should always be noted.

Presence of haemoglobin and methaemoglobin in the serum of post transfusion sample of blood should be checked. Urine examination includes checking presence of haemoglobin in urine. Microscopic examination of urine for red cell casts. In case of death, post-mortem Examination is must. Pathological examination of viscera will show changes in renal tissue. In intravascular haemolytic reactions, the kidneys will show haemoglobinuric nephrosis. Acute tubular necrosis and casts of haemoglobin in the tubules is seen. These kidneys are called transfusion kidneys.<sup>16</sup>

## 5. Suggestions

To avoid legal complications the professionals dealing with blood transfusion must follow the national guidelines. There should always be a standard operating procedure of procuring, issuing and administering blood to the patient for each institution.<sup>17</sup> It is recommended that following things should be done carefully:

1. There should always be an informed, written and witnessed consent.
2. Labelled Blood sample be sent for grouping and matching and this fact should be recorded.
3. Written documentation of all parameters like from where blood for transfusion was obtained, grouped, and matched.
4. Check that all the required tests have been done on the blood which is being transfused.
5. Cross Check the labels properly for blood group with that of patient.
6. Do not administer blood and drugs through a common administration set.
7. In case of reactions always treat promptly and document all findings thereof.
8. Always inform the blood centre in case of ADRs, along with sign and symptoms of the patient.
9. In case of death do not panic and always inform the police and keep the patient record securely.

## 6. Conclusions

One must take care of the all the recommendations to minimize the medico-legal adversaries related to blood transfusion, which includes informed consent of donor as well as patient, proper documentation, and accurate investigations. Transfusion is a well-accepted procedure in modern day clinical practice. Need of the hour is proper knowledge of the rules and law and following the ethical guidelines of blood transfusion. Appropriate legislation, regulations, policies, and guidelines are important so that right blood is given to the right patient at the right time and place.

## 7. Conflict of Interest

None.

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