

Ethical and legal aspects of transfusion medicine- review literature

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Introduction

Blood is a 'drug' under section 3(b) of the Drugs and Cosmetic Act (D and C Act), 1940 and Drugs and Cosmetics Rules, 1945.⁽¹⁾ This Act and the Rules thereof provide the legal framework for regulating the functions of blood banks, which determine the quality of the blood transfusion services in India.⁽²⁾

Blood transfusion is a cornerstone of modern clinical practice.^(3,4) Blood or blood components must be ordered and administered safely and appropriately. Transfusion is process rather than a single discrete event. It begins with donor considerations (whether their donation is safe and whether it is safe for any patient to receive). Once blood is collected, infectious disease testing, compatibility testing, necessary modifications such as irradiation or leukocyte reduction are to be taken care of. The end-point of the transfusion process involves proper matching of the recipient and the unit, appropriateness of blood as the best treatment modality, administration and evaluation of the recipient).⁽⁵⁾

The provision of blood and blood products from donation to transfusion must be based on sound ethical principles and quality guidelines.

Framework of Indian Transfusion Services

Indian Transfusion services are controlled by the drug inspector and National Aids Control Organization (NACO).⁽⁶⁾

Drug controller (The regulatory authority): In 1993, licensing of blood banks was made mandatory by the Supreme Court of India. The license has to be renewed on expiry. The most important point is that blood from voluntary blood donor in outdoor camps can only be collected either by a licensed Government Blood Bank, or a licensed Regional Transfusion Centre designated by State Blood Transfusion Council constituted by the State Government.

The procedure for licensing of blood banks 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.⁽⁷⁾

National Aids Control Organization (NACO): NACO frame guidelines for Blood transfusion. The National Blood Policy is an offshoot of the National

Aids Control Program.⁽⁸⁾ NAC plays a pivotal role in infrastructure development, setting up component separation units, promoting voluntary blood donation, training staff etc.⁽⁹⁾

National blood policy: The National Blood Policy⁽¹⁰⁾ (NBP) -2002 documented strategies for improving transfusion services. It also outlined methods for motivation and ethical clinical use of blood. Further, it is also attempted to eliminate profit making motive in blood banks.

Fundamental rights of the Constitution under Article 21 states that no person shall be deprived of his life. Blood transfusion can be life saving and also 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.

Consumer Protection Act

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

Ethics and 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:-

A. Related to Blood Centres: Donors and Donations

1. Donations shall be voluntary and non-remunerated 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 be in compliance with 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.

B. 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. In the event that 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 particular components be used that are appropriate and optimally safe.
7. Blood transfusion should be in compliance with this code of ethics.

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 are blood bank'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. For instance, According to American Association of Blood Banking, written consent of the prospective donor is must after the procedure is explained in terms the donor can understand.

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. Once the donor provides informed consent, he still retains the right to sue if negligent acts by blood bank result in harming him. Use due care in testing and screening the donors is an obligation owed to the recipient of the transfusion.

Deaths related 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 the 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.⁽¹²⁾ In an emergency procedure may be exempted but it must 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 of time as per the laws.⁽¹³⁾

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.⁽¹⁴⁾ 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. It is better to inform the patient about transfusion before operations.⁽¹¹⁾

Nurses should be trained in transfusion but doctor must be able to intervene quickly if need arises.⁽¹²⁾

Investigations

Investigation should be done without delay to reach at informative and valuable conclusions. First thing to see is there is no clerical error in collecting or transfusing blood to a wrong person. Blood grouping from the bag and patient should be repeated to rule out any error in grouping. Regrouping is performed pre transfusion 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.⁽¹⁵⁾

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.

Haematological examination

Presence of haemoglobin and methamoglobin in the serum of post transfusion sample of blood from patient indicates intravascular hemolysis. But contaminated samples of blood obtained during post-

mortem are not good due to post-mortem lysis of red cells.⁽¹⁶⁾

Urine examination

Presence of haemoglobin in urine shows intravascular hemolysis. Urobilin and urobilinogen may be present. Sediments from centrifuged sample show red cell casts.

Post-mortem Examination

Pathological examination of viscera will show changes in renal tissue. In intravascular haemolytic reactions, the kidneys will show haemoglobin uric nephrosis. Acute tubular necrosis and casts of haemoglobin in the tubules are seen, so called as transfusion kidneys.⁽¹⁶⁾

Recommendations

To avoid legal complications the professionals dealing with blood transfusion must follow the national and international guidelines. There should always be a standard operating procedure of procuring, issuing and administering transfusion for each institution. It is recommended that following points should be carefully followed:

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. Keep the records: from where blood for transfusion was obtained, grouped and matched.
4. Please see 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 particular patient.
6. Do not administer blood and drugs through a common administration set or inject drugs.
7. In case of reactions always treat promptly and document all findings thereof.
8. Always inform the blood bank 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.

Conclusions

One must Take care of the all the recommendations so as to minimize the gravity of the medico-legal adversaries during his career. Proper documentation is must in Blood transfusion. It is a well accepted procedure in modern day clinical practice and the need of the hour is to be well versed with the law and follow the ethical guidelines of blood transfusion.

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