

## ARTICLES

## Ethical issues in transfusion medicine

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**Abstract**

*The practice of transfusion medicine involves a number of ethical issues because blood comes from human beings and is a precious resource with a limited shelf life. In 1980 the International Society of Blood Transfusion endorsed its first formal code of ethics, which was adopted by the World Health Organisation and the League of Red Crescent Societies. A revised code of ethics for donation and transfusion was endorsed in 2000. Blood donation as a gift, donor confidentiality, donor notification and donor consent, consent for transfusion, the right to refuse blood transfusion, the right to be informed if harmed, and ethical principles for establishments, are discussed in the international and Indian contexts.*

Ethics is basically a set of moral values or a code of conduct. The role of ethics in developing clinical practice guidelines and recommendations for health-care providers is to ensure that values that may not be adequately incorporated into the law are given reasonable consideration. The framers and the users of guidelines must be aware of the potential ethical conflicts inherent in many medical decisions, and the guidelines must reflect a thoughtful consideration and balancing of issues.

The practice of transfusion medicine involves a number of ethical issues because blood comes from human beings and is a precious resource with a limited shelf life. It involves a moral responsibility towards both donors and patients. Decisions must be based on four principles: respect for individuals and their worth, protection of individuals' rights and well being, avoidance of exploitation, and the Hippocratic principle of *primum non nocere* or "first do no harm".

**History of transfusion ethics**

Ethics is a dynamic process in relation to the state of scientific knowledge, public awareness and the local laws, at any given time and place. This is clear when we review the history of transfusion ethics (1). The earliest mention of human transfusion, in 1492, describes efforts to save the life of Pope Innocent VIII. Blood was extracted from three 10-year-old boys and transfused to the Pope. All three boys and the Pope died. Some two centuries later transfusion was attempted again. In 1667, Dr Richard Lower transfused sheep's blood to a mentally-ill man to cure him. The patient was given 20 shillings to undergo this experiment. The same year a 34-year-old man underwent repeat transfusions of calf's blood. This resulted in a classical haemolytic transfusion reaction and the court banned future transfusions.

Human-to-human transfusion was resurrected by James Blundell, a London obstetrician, to save the lives of women with obstetric haemorrhage. By the early twentieth century, a

number of advances had been made in transfusion medicine, in the form of the discovery of blood groups and preservation, making transfusion safer. HIV brought transfusion safety into public awareness. It also brought up ethical issues in relation to both donors and patients.

After approximately 1,000 transfusion/fraction-transmitted HIV infection cases occurred in 1982-83, in 1992 the Krever Enquiry (2) ruled that the Canadian Red Cross (CRC) erred in not barring gay men from donating blood when it was known that AIDS was almost exclusively a disease of gay men, and the American Association of Blood Banks had debarred them from donating blood. The CRC replied that it was trying not to discriminate against gay people. The court upheld that "public rights are higher than the individual's right".

**ISBT code of ethics**

In 1980 the International Society of Blood Transfusion (ISBT) endorsed its first formal code of ethics. It was later also endorsed and adopted by the World Health Organisation and the League of Red Crescent Societies. A revised code of ethics for blood donation and transfusion was endorsed in 2000, with inputs from various concerned organisations. It gave recommendations regarding the ethical responsibilities of the donor, the collection agency and the prescribing authority toward the well being of the recipient and the community at large (3). This code is reproduced below:

**A code of ethics for blood donation and transfusion**

*The objective of this code is to define the ethical principles and rules to be observed in the field of transfusion medicine.*

- 1. Blood donation, including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.*
- 2. 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. Any valid advance directive should be respected.*
- 3. 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.*
- 4. A profit motive should not be the basis for the establishment and running of a blood service.*

5. *The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.*
6. *Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.*
7. *The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.*
8. *Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practised.*
9. *Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.*
10. *All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.*
11. *Donors and recipients should be informed if they have been harmed.*
12. *Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.*
13. *Genuine clinical need should be the only basis for transfusion therapy.*
14. *There should be no financial incentive to prescribe a blood transfusion.*
15. *Blood is a public resource and access should not be restricted.*
16. *As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.*
17. *Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.*
18. *Blood transfusion practices established by national or international health bodies and other agencies competent and authorised to do so should be in compliance with this code of ethics.*

Some important issues are being highlighted:

### **Ethical issues related to donors**

*Blood donation as a gift:* The WHO recommends that national blood services should be based on voluntary, non-remunerated blood donation. No one should be forced to donate, for family or economic or any other reason. The trade of human blood and body parts is unethical. "The dignity and worth of the human being should be respected." (4)

Non-remunerated blood donation is considered a gift and the blood centre has a right to accept or defer it if unacceptable. Donor deferral might appear as discrimination and a violation

of a human right, but the patient's right to safer blood is more important than the donor's right to not to discriminated against, as blood centres are made to help patients and not donors.

*Donor confidentiality, donor notification and donor consent:* Donor confidentiality is an important issue. Personal information disclosed by the blood donor during the course of a pre-donation interview and information obtained from the various tests performed on the donated component, are expected to be held in confidence by the donor centre (4).

Donor screening and testing used to be simple. Today's donors are asked intimate questions about their lifestyles and put through a battery of laboratory tests. This has had significant repercussions for the relationships between blood centres, blood donors, physicians and patients. The blood donor, an ostensibly healthy individual until notified of an abnormal result by the blood centre, may seek a physician's advice and doubt the creditability of the testing procedure and deferral policies. A more specific test might turn out to be negative and the donor may be labelled as healthy. This donor might return to the blood centre asking for compensation for the unnecessary mental anguish and the expenses incurred and might never donate again.

The donor room personnel and the donor may have misunderstandings about confidentiality. There is often a tension in donor centres between the need to keep the donor information confidential and the need to disclose relevant information to third parties such as family members, employers, public health authorities and police officers.

Blood safety depends partly on the information provided by the donor and it is also the donor's ethical duty to provide truthful information. It is unethical to wilfully conceal information about high-risk behaviour or medical history.

### **Ethical issues related to patients**

Ethical issues related to patients include access to risk-free safe blood free of charge or need of replacement, informed consent for transfusion, the right to refuse the transfusion, and the right to be informed if harmed.

*Consent for transfusion:* Consent for transfusion has to be informed consent (5). The patient should be informed of the known risks and benefits of transfusion, and alternative therapies such as autologous transfusion or erythropoietin. Only then should the consent be documented. If the patient is unable to give prior informed consent, the basis of treatment by transfusion should be in the best interests of the patient.

*Right to refusal:* The patient's right to refuse blood transfusion should be respected (6). Some religious sects such as Jehovah's Witnesses do not accept blood transfusions (7). Followers of this belief live in India as well and there have been instances of blood refusal here.

*Right to be informed if harmed:* If the patient has been transfused blood and components that were not intended for him/her, whether harmed or not, he/she has the right to be informed (6, 8). Similarly a patient who has inadvertently received blood

positive for a transfusion transmissible marker has a right to be informed and given due compensation.

*Ethical principles for blood establishments:* A profit motive should not be the basis of establishing and running blood transfusion services. Wastage should be avoided to safeguard the interests of all potential donors and recipients (3).

### The situation in India

With the rising awareness of ethical issues in every field of medical care and research in India, awareness is growing in the field of transfusion medicine as well. But we are nowhere near the international code of ethics.

In the 1990s, in response to a public interest litigation a Supreme Court order banned professional blood sellers and directed the government to formulate a national blood policy. The National Blood Transfusion Council, with the National Blood Policy as a tool, and the Drugs Controller, with the help of the Drugs and Cosmetics Act, now aim to ensure blood safety and ethical transfusion practices in India.

Currently under the Drugs and Cosmetics Act it is mandatory to test blood for anti-HIV 1 and 2, anti-HCV, HBsAg and RPR for syphilis (9). Consent for testing is taken and the donor is given the option of receiving the results – this is mandatory in some countries such as the US and UK.

Until recently donors were not informed because specific consent for testing was not taken (10), and the screening tests had relatively high false positive rates, which could cause panic. No confirmatory tests were required. So the donation system was projected as anonymous and unlinked and adequate counselling was not available. The National Blood Policy of 2002 has addressed this gap (11).

The Code of Medical Ethics, that is binding on doctors, honours confidentiality. However, in a court of law in India, this privilege is not absolute but qualified. Doctors can reveal information in

the interest of individual or general welfare of society and when there is no mal-intention.

Ethical issues are mostly violated in relation to the patient in India. Patients all over the country do not have access to safe blood, free of charge, or the option of giving consent and choosing safer alternatives. With the National Blood Policy, a decision was taken to improve transfusion services all over the country and create greater awareness about transfusion issues. The policy must also address all the other issues in the international code of ethics for blood donation and transfusion to make India achieve international standards.

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