Review

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Role of Ethics in Blood Transfusion Practice

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Introduction

No physician today, including and especially the surgeon, treats his or her patient unaware of the legal responsibilities and potential consequences should an adverse outcome occurs. The tragedy of transfusion-related acquired immunodeficiency syndrome (AIDS) has given rise to new approaches for determining whether a transfusion is necessary, whether additional options are available to the patient, or whether special informed consent is required for the transfusion. These and other cases have helped redefine responsibilities to patients, threatened to redefine what and who determines the appropriate standard of care, and spawned new and sometimes novel procedures for avoiding and managing transfusion-related medical malpractice claims[1].

In a legal sense, a legal claim is a demand for compensation. A medical malpractice claim arises from the negligent provision of medical services. Usually, such claims are accompanied by lawsuit, although as indicated below, increasingly claims are being resolved out of the courts. All lawsuit is brought by a plaintiff, that is, the injured patient or, if the patient has died, the estate[1]. Sometimes other plaintiffs, for example, the spouse or minor children, may bring derivative claims for personal injuries. Such as the secondary transmission of blood borne infections[1].

Understanding when and why a plaintiff can prevail in a malpractice lawsuit can help a physician better know what actions should be taken before and during the delivery of a medical service. Our justice system, unfortunately, uses the terms winners and losers, although victims are often winners and losers can become victims. For the plaintiff to win, he or she must prove each of the following elements[2]:

1. The defendant owed the plaintiff a duty to use reasonable care (also known as due care).
2. The defendant breached this duty
3. The plaintiff was injured
4. The defendants breach the plaintiff's injury.

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[3]. 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 "premium non nocere" or "first do no harm[1].

History of ethical practice in Blood transfusion

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. The earliest mention of human transfusion, in 1492[1], 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[1] transfused

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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[2], a London-based obstetrician, to save the lives of women with obstetric haemorrhage. By the 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.

ISBT code of ethics

In 1980 the International Society of Blood Transfusion (ISBT[4]) endorsed its first formal code of ethics. It was later also endorsed and adopted by the World Health Organisation (WHO[4]) 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 organizations. It gave recommendations regarding the ethical responsibilities of the donor, the collection agency and the prescribing authority towards the well being of the recipient and the community at large. This code is discussed as follows.

A code of ethics for blood donation and transfusion[5]

1. Blood donation, including haematopoietic shall, in all circumstances, be voluntary and non-remunerted; 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[5].
2. Patient 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. Blood transfusion practices established by national or international health bodies and other agencies' competent and authorized to do so should be in compliance with this code of ethics.
5. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.
6. 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.
7. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.
8. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
9. 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 practiced.
10. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.

Ethical issue related to donors[6]

1. 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, economic or any reason. The trade of human blood and body parts is unethical. The dignity and worth of the human being should be respected.
2. Donor confidentiality, donor notification and donor consent: Donor confidentiality is an important issue. Personal information disclosed by the blood 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.
3. 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 willfully conceal information about high-risk behaviour or medical history.

Ethical issues related to patients[7]

1. Consent for transfusion : Consent for transfusion has to be informed consent. 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 interest of the patient.
2. Right to refusal : The patient's right to refuse blood transfusion should be respected. Some religious sects such as Jehovah's Witnesses do not accept blood transfusions. Followers of this belief live in India as well and there have been instances of blood refusal here.
3. 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 interest of all potential donors and recipients.

The Indian situation[8]

1. In the 1990s, in response to a public interest litigation 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 aims to ensure blood safety and ethical transfusion practices in India[8].
2. 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. 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.
3. Until recently donors were not informed because specific consent for testing was not taken and the screening tests had relatively high false positive rates, which could cause panic. No confirmatory tests were required[7]. 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[8].

Conclusion

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 poviders 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[1].

Ethical issues are mostly violated in relation to the patient in India[1]. Patients all over the country do not have access to safe blood, free of change, 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.

We, at R L Jalappa Hospital and Research Center, Tamaka, Kolar, strictly adhere to the international code of ethics regarding blood transfusion.

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