

ETHICAL CHARTER OF BLOOD DONATION

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1.ETHICAL BACKGROUND

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 Organization 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 contexts. 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.

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.” 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 centers are made to help patients and not donors.

The field of blood donation and transfusion nowadays plays in a rapidly growing global world with increasing needs for continuous monitoring of new threats and challenges. Simultaneously necessary ethical discussions rise on medical, financial, and political aspects.

2. DEFINITIONS

Blood Whole blood collected from a single donor and processed either for transfusion or further manufacturing.

Donor Someone who voluntarily gives blood or blood components.

Regular donor Someone who made at least two donations within the last 24 months. The last donation has been made within the last 12 months.

Voluntary non remunerated blood donation. A donation is considered voluntary and nonremunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money.

Blood product shall mean any therapeutic product derived from human blood or plasma.

Blood components Therapeutic components of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration and freezing using conventional blood bank methodology.

Blood donation The result of collecting whole blood or blood components from an individual in a single procedure; a donation is counted from the point of skin puncture onwards.

Blood establishment shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks.

Deferral shall mean suspension of the eligibility of an individual to donate blood or blood components such suspension being either permanent or temporary.

Haemapheresis A procedure in which blood is drawn from a donor and separated into its components, some of which are retained, such as plasma or platelets, and the remainder returned by transfusion to the donor.

Hematopoietic tissue Blood-forming tissue, consisting of reticular fibers and cells.

3. ETHICAL PRINCIPLES OF BLOOD DONATION

Donor management carries a two-sided moral responsibility towards both donors and blood product recipients. Policy and donor management decisions are founded on following principles of ethics.

- Respect for individuals and their autonomy
- Protecting individuals' rights and well being
- The Hippocratic principle of *primum non nocere* or 'first, do no harm'

In donor management, some special ethical issues arise and can be divided into two groups.

Commercial considerations: There is a lengthy and heated debate on the permissibility of trading one's own blood. Given that blood products derive from non-remunerated donations, how can one avoid exploitation and ensure distributive justice if such products then enter a commercial chain?

Mistreatment of donors and prospective donors: Blood is a sensitive matter, and perceived or true mistreatment of donors can have a strong impact on public and political discussions.

3.1 The donation of whole blood or its components

3.1.1 Blood is a public resource and access should not be restricted.

3.1.2 Blood donation, including hematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor.

3.1.3 All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.

3.1.4 In keeping with the principle of distributive justice, implying universal access to blood products, the donor has no say in determining the destination of the blood products derived from the donation. It is up to the doctor in attendance to decide how to administer the blood products. There are two exceptions to this rule.

- **Personal use:** Donors can make an autologous donation, i.e. a donation for therapeutical use in themselves. Then, the blood products can only be used for that purpose
- **Research:** With direct informed consent, a donation can be used for nontherapeutic purposes, e.g. research. The donor has the right to grant permission for this purpose, not to change or modify its use.

3.2 Donor confidentiality

3.2.1 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 blood transfusion centre.

3.3 Information and notification

3.3.1 An increasing number of tests are developed to improve the safety and efficacy of blood transfusion. The donors should be informed about the selection procedure and kind of tests that performed before and after donation and possible unexpected test results. This information to the donor is mandatory.

3.3.2 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.

3.3.3 The donors should be informed about All the possible risks of blood, blood products, or stem cell donation. This information can be included in the information of donors and recipients as part of the informed consent

3.3.4 Donors and recipients should be informed if they have been harmed.

3.3.5 The blood establishment must notify a donor for of any important result or findings that arise during or after the visit to the blood establishment, abnormal results from the biometrics or medical examination, hereditary predispositions-/diseases, any other accidental finding that can be considered to be important to the donor or his/her family or acquaintances

3.4 Inform Consent

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

3.5 Anonymity

The identity of the donor and recipient are managed in accordance with the privacy policies and only by authorised professionals. The anonymity of the donor and the recipient are of major strength of the voluntary blood donation. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.

3.6 Freedom of choice

Blood donation is a free and informed choice aimed at protecting the health of patients and thus consistent with public health programming provisions.

3.7 Gratuitousness and non-profit rule

Donating blood is voluntary at all time (free of charge) and cannot be remunerated in any way. Whole blood and blood components cannot be a source of profit.

3.8 Safety

3.8.1 Selection of voluntary blood donors through pre-donation check and post –donation test ensure the safety of the blood transfused to patients and the protection of the health of the donors.

3.8.2 The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient. 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 behavior or medical history.

3.9 Periodicity

3.9.1 The regular voluntary blood donation is a guarantee of reliability and safety for the recipient as well as of the certainty of supplies. The regular blood donor is checked periodically, whenever donates blood by accurate and careful medical visit and testing.

3.9.2 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.

3.10 Accountability

Donors protect the safety of transfused patients through adopting adequate lifestyles and answering to the call-to-donate only when there is absence of risks for the health of others.

3.11 Treating the donor respectfully

Staff must observe general etiquette. There is no difference of opinion on that, although cultural diversity may lead to differences on what is considered appropriate.

4. Voluntary Associations and Non-Governmental Organisation active in the field of blood donation

4.1 Effectiveness

Associations of voluntary blood donors and NGOs active in the field of blood donation pursue the rational and good use of donated blood, promoting the right to health of donors and of patients in the needs of transfusion therapy.

4.2 Self-sufficiency

Associations and NGOs active in blood donation address citizens' health needs promoting the achievement of self-sufficiency in blood and blood components at national level while improving the quality and safety of collected blood and its rational and proper use.

4.3 Inclusiveness

Associations and NGOs promoting blood donation should be nonpartisan, non-confessional, not-for-profit, and reject any discrimination based on gender, ethnos, race, language, nationality, religion or political ideology in compliance with national and international legislations.

4.4 Solidarity

Associations and NGOs active in blood donation enhance the diffusion of voluntary, periodic, associated, unpaid, anonymous and aware donation of whole blood and blood components as it is an universal humanitarian value and the expression of civic solidarity. The blood donor is the promoter of a basic health and social service and should be considered as a driver for the dissemination of the values of solidarity, generosity, social and civic participation and protection of the right to health.

4.5 Awareness

The organisations committed to blood donation promote the circulation of information and the improvement of people's health education as well as the adoption of healthy lifestyles by donors and, more generally, by the whole population.

4.6 Complementarily with health programmes

Associations and NGOs must harmoniously cooperate with each other and with National and Regional Health Services commonly pursuing the goals set in national and international health programmes.

4.7 Openness to the world

Associations and NGOs promote the development of voluntary associations committed to blood donation at national and international level and promote and participate in international cooperation projects aimed at improving the health conditions of people in needs of blood transfusion therapy.

5. Public Authorities, Institutions and other organisations

5.1 Acting in Accordance with Laws and Regulations

As a general rule and in all circumstances, Public Authorities and stakeholders must observe the international, European, national, local regulations and ethical and professional codes of practice applicable to blood donation.

5.2 Commitment and respect

The organisations active in the governance of blood donation commit to reconcile the efficiency and sustainability of their performances with respect for the volunteer blood donors while providing essential services for patients.

5.3 Cohesion and cooperation

Policy actors in the field of blood donation mobilise all their strengths in a shared spirit of teamwork and solidarity to make donated blood a sustainable source of health and social capital. To reach these goals, they are open to engage in programme of scientific, technical, and cultural cooperation in Europe, the neighbouring Countries and abroad, in a spirit of partnership.

5.4 Extensive involvement

All employees of the organisations involved in blood donation are expected to make this ethical standards an integral part of the way they do their jobs. The organisation should encourage the dissemination of practices consistent with the ethical framework of this charter.

6. COMMON LEGAL AND REGULATORY REFERENCES

6.1 Article 25 of the "Universal Declaration of Human Rights" - Article 11 and 13 of the "European Social Charter 1961";

6.2 Article 12 of the "UN International Covenant on Economic, Social and Cultural Rights", 1966;

6.3 Resolution no. 23 World Health Organization, 1970, which are fully reflected in the principles of the Constitution (Articles 2 - 3 - 32);

6.4 "Charter of Patients' Rights", adopted in 1973 by the American Hospital Association;

6.5 "Charter of Patients' Rights", adopted by the CFE in Luxembourg on 6th to 9th May 1979;

6.6 Chapter VII of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine adopted in Oviedo on 4th April 1997.

6.7 International Society of Blood Transfusion. A code of ethics for blood donation and blood transfusion. 2006 June 15. Available from: http://www.isbt-web.org/files/documentation/code_of_ethics



6.8 Ethical issues in transfusion medicine. Bethesda: American Association of Blood Banks Press; 2000. Macpherson CR, Domen RE, Perlin T.

6.9 Ethical Aspects of Blood Donors and the Recipients of Their Blood. Hindawi Publishing Corporation Journal of Blood Transfusion, Volume 2012, Article ID 606753, 4 pagesdoi:10.1155/2012/606753)

6.10 Donor Management manual. Section 13.1 Ethical issues in blood donation. 2010

6.11 International Society of Blood Transfusion. A code of ethics for blood donation and transfusion. Retrieved 19 March 2010 from <http://www.isbt-web.org/files>

6.12 Macpherson CR, Domen RE & Perlin T (2001). Ethical Issues in Transfusion Medicine. Bethesda, Maryland, AABB Press

6.13 Council of Europe. Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. CETS No.: 164

6.14 Directive 2002/98/EC of The European Parliament And of The Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

7. LIST OF SIGNATORIES