CODE OF ETHICS RELATING TO TRANSFUSION MEDICINE

Purpose

This Code defines the ethical and professional principles that the International Society of Blood Transfusion (hereinafter the Society) as a body of transfusion medicine professionals believes should underpin the establishment and activities of a Blood Service and identifies ethical and professional standards for practitioners active in the field.

Introduction

The availability of a safe, effective and sufficient supply of blood and blood products (hereafter defined as '*blood*') as well as their optimal use for patients, underpins the practice of modern medicine. *Blood* is a medical product of human origin and its availability is dependent on the contribution of the *donor* who gives *blood* for the benefit of others with no physical benefit to her/himself. It is therefore important that the contribution of the *donors* and their donation is respected and that all reasonable steps are taken to protect their health and safety and that appropriate safeguards are in place to ensure that the products derived from the donation are used appropriately and equitably for the patients.

The Society endorses the principles contained in the *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* (Oviedo Convention 1997)[1] and also the recommendations contained in the *World Health Assembly Resolution on the Utilization and supply of human blood and blood products (WHA28.72)*[2]. Consistent with this we affirm the importance of the principle of voluntary non-remunerated donation as the basis for the establishment and development of Blood Services.

Blood Services provide *blood* for patients and information and advice to clinicians to support the appropriate use of *blood.* The rights and responsibilities of *donors* and patients are of equal importance and the health, safety and well-being of the *donor* should not be compromised in order to meet the needs of patients.

This Code of Ethics outlines the responsibilities of *Professionals* involved in the field of transfusion medicine to *donors* and to patients. These responsibilities are aligned to the well acknowledged four principles of biomedical ethics: autonomy, non-maleficence, beneficence, and justice. A specific aspect of another principle, dignity, covering all four principles, specifically applies to *donors* (all five key ethical principles are shown in the table below).

The Code also includes a series of statements directed to health authorities that relate to the stewardship of the blood supply. The Society expects that Professionals involved in the field will, to the extent within their control, also adhere to the principles contained in this section of the document.

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[1] Council of Europe CETS No 164 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 http://www.coe.int/en/web/bioethics/oviedo-convention

[2] *World Health Organisation: Resolution 28.72 on the utilization and supply of human blood and blood products 1975. http://www.who.int/bloodsafety/en/WHA28.72.pdf*

Ethics - 'the branch of knowledge that deals with moral principles'[3]	
Dignity	A human being has an innate right to be valued and receive ethical treatment.
Autonomy	The capacity of a rational individual to make an informed, un-coerced decision.
Beneficence	Beneficence is action that is done for the benefit of others. Beneficent actions can be taken to help prevent or remove harms or to simply improve the situation of others
Non maleficence	To "do no unnecessary or unreasonable harm."
Justice	Concerned with the equitable distribution of benefits and burdens to individuals in social institutions, and how the rights of various individuals are realised.

1. Definitions

1.1 "*Blood*" means human blood that is collected, including whole blood and blood components collected by apheresis and hematopoietic stem cells, either for direct transfusion or for use in the preparation of a medicinal product for human use.

1.2 ***"Donor"*** means any person who voluntarily gives blood or blood components

1.3 ***"Blood Service"*** means any structure or body that is responsible for any aspect of the recruitment of *donors*, collection and testing of *blood*, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion.

1.4 ***"Professional"*** means any professional involved in either the activities of a Blood Service or in the clinical use of *blood*.

The use of the terms 'must' and 'should' have been carefully controlled within this document. The term 'must' identifies something as mandatory. A *professional* will have the ability to control if this can be achieved. In contrast 'should' identifies a term where either the principle is outside of the control of the *professional* (i.e. a stewardship statement) or where the ability of the professional to make a decision might, in individual cases, be constrained by external factors such as public health or legal requirements and resourcing decisions.

[3] Definitions derived from *Human Bodies: Donation for medicine and research. Nuffield Council on Bioethics* http://nuffieldbioethics.org/wp-content/uploads/2014/07/Donation_full_report.pdf

2. Ethical Principles Relating to Patients

In addition to equitable access to treatment, the patient has a right to expect that her/his autonomy is respected, and that a decision to transfuse is made for her/his benefit and avoids the risk of unnecessary or unreasonable harm to her/him.

2.1 Autonomy

2.1.1 Specific consent must, where feasible, be obtained prior to the transfusion. The consent should be informed and in order to achieve this, information must be provided on the known risks and benefits of blood transfusion and any possible alternative therapies in order to enable a decision whether to accept or refuse the procedure. The information must be provided in a way that is comprehensible to the potential recipient.

2.1.2 In the event that specific consent cannot be obtained the basis for treatment by transfusion must be in the best interests of the patient.

2.1.3 Any valid advance directive should be respected.

2.2 Beneficence and non-maleficence

2.2.1 The patient has a right to be treated with dignity and therefore decisions on the need for transfusion should be based on genuine clinical need.

2.2.2 Transfusion therapy must be given under the overall responsibility of a registered healthcare Professional who is competent to do so.

2.2.3 Patients should be informed if information becomes available following a transfusion that indicates they have, or may have been, harmed by the transfusion.

2.2.4 Information concerning the patient and the treatment that they receive should be managed in a confidential manner.

2.3 Justice

2.3.1 Patients should be treated equitably for the same healthcare condition. This implies that medical decisions relating to transfusion of *blood* should be based on the best available evidence and treatments for patients (adapted to the local healthcare situation).

2.3.2 The patient should, within the constraints of the local health system, receive the most appropriate blood product(s) that is (are) available. As far as possible the patient should receive only those particular products (whole blood, cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.

2.3.3 There should be no financial incentive to prescribe *blood*.

3. Ethical Principles Relating to Donors

The autonomy and dignity of the *donor*, including potential *donor*s, must be respected at all times. The *donor* does not physically benefit from the donation, thus the *donor* should be exposed to as little harm as possible, in compliance with the principle of non-maleficence.

3.1 Autonomy

3.1.1 The *donor* must expressly provide consent to the donation of *blood*. The consent must be informed. Informed consent should include: knowledge of all known risks associated with the donation, of the subsequent legitimate use of the donation and of how information pertaining to the *donor* and donation will be treated confidentially. The consent should, where appropriate, include information on possible commercialisation of the products derived from the donation and whether the donation might be used for research, quality control or any other purpose.

3.1.2 Information provided by the *donor* and generated about the *donor* (i.e. test results) *must* be treated confidentially. The d*onor* should be informed in advance of the release of any such information.

3.2 Dignity and non-maleficence

3.2.1 Donor selection criteria must be applied to protect the health of recipients and *donors*. *Donors* must be made aware of their responsibility not to harm the recipient

3.2.2 *Donors* must be informed if they have, or may have been harmed or in the event that any results or information regarding their donation may have an impact on their health.

3.2.3 The decision to administer any substance or medicine to a *donor* for the purpose of increasing the concentration of specific components of the blood or for any other reason should take into account that there is no benefit to the *donor*. This should only be considered when there is good evidence of specific benefits to the recipient, or in the context of research approved by an Ethics Committee and when the *donor* has been informed of all known risks and these have been reduced as far as is possible.

3.2.4 Anonymity between *donor* and recipient should be ensured except when both *donor* and recipient freely and expressly consent otherwise.

4. Stewardship

Health authorities have a responsibility to ensure that *Blood Services* are established and progressively developed so as to assure the needs of the patients using an ethical framework encompassing the care of both *donors* and patients.

The Society endorses the principles contained in the *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* (Oviedo Convention 1997)[1] and also the recommendations contained in the *World Health Assembly Resolution on the Utilization and supply of human blood and blood products (WHA28.72)*[2]. Consistent with this we affirm the importance of the principle of voluntary non-remunerated donation as the basis for the establishment and development of Blood Services.

The Society therefore urges Health Authorities to ensure that the activities of *Blood Services* are undertaken in a manner consistent with the contents of this Code of Ethics and that in addition the following key principles should underpin their governance and delivery.

4.1 Dignity and Beneficence

4.1.1 Donated *blood* should be seen as a 'community good' in order to assure the dignity of the *donor* and of their donation and not as a commodity to meet others' ends. Therefore, the establishment and running of a *Blood Service* should be based upon not-for-profit principles.

4.1.2 Blood donation should be voluntary and non-remunerated[2]. A donation is considered voluntary and non- remunerated if the person gives *blood*, 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. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation[4].

4.1.3 Any form of incentive[5] that might influence the underlying reason to donate *blood* should be actively discouraged and must be prohibited if this will either impact on the safety of the *blood*, result in exploitation of the *donor* or lead to inequity of access for recipients

4.1.4 Donation is a civic act for the benefit of others and contributes to social cohesion. There is no right to donate.

4.1.5 Blood donor selection should be based on current, accepted and regularly reviewed scientific data. The ability to donate should not be unnecessarily restricted and blood donation criteria should not be justified on the basis of gender, race, nationality, religion, sexual orientation or social class.

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[1] Council of Europe CETS No 164 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 http://www.coe.int/en/web/bioethics/oviedo-convention

[2] *World Health Organisation: Resolution 28.72 on the utilization and supply of human blood and blood products 1975. http://www.who.int/bloodsafety/en/WHA28.72.pdf*

[4] *Council of Europe Definition contained in Article 2 of Recommendation No R (95)14*

[5] *Based on the Intervention Ladder contained in Human Bodies: Donation for medicine and research. Nuffield Council on Bioethics http://nuffieldbioethics.org/wp-content/uploads/2014/07/Donation_full_report.pdf*

4.1.6 Neither *donor* nor potential recipient has the right to require that any such discrimination be practiced.

4.1.7 No coercion should be made on the *donor* to give blood

4.2 Justice

4.2.1 *Blood* and blood products should be considered as a public resource. Access to the products should be based on clinical need taking into account the overall capacity of the local health system. Discrimination based on factors such as patients' resources should be avoided.

4.2.2 Wastage of *blood* should be avoided in order to safeguard the interests of all potential recipients and the *donor*.

4.3 Non-maleficence

4.3.1 All matters related to donation of *blood* and its clinical use should be in compliance with appropriately defined and internationally accepted standards.

The original Code was adopted by the General Assembly of ISBT, July 12, 2000.
It was amended by the General Assembly of ISBT, September 5, 2006.
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