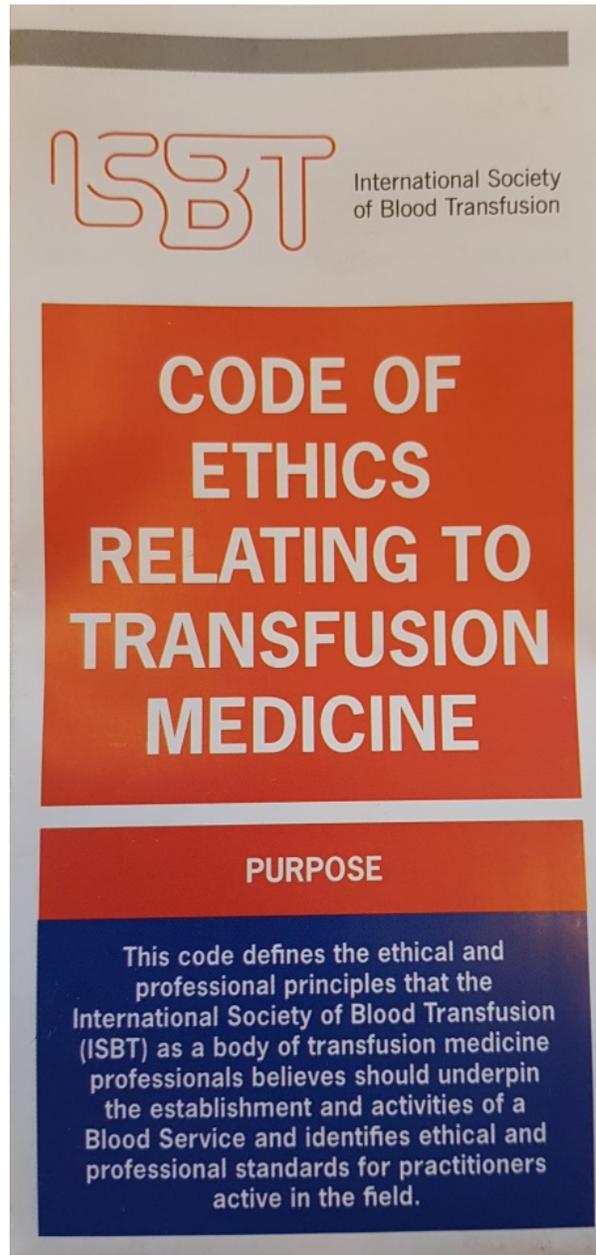




The ISBT Code of Ethics – ethical principles and rules to be observed in the field of transfusion medicine

Judith Chapman, ISBT Executive Director



Outline of Presentation



- What it is
- Background to the Code
- Drivers to review of the Code in 2014
- Structure of the 2017 Code
- Definitions
- Content of the 2017 Code
- What's Next!

<http://www.isbtweb.org/about-isbt/code-of-ethics>

The ISBT Code of Ethics



The code defines the ethical and professional principles that ISBT 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.

It can be considered as a code of practice for professionals and as an advocacy tool.

Code of Ethics for Blood Donation & Transfusion



- ISBT founded in 1935
- Ethics Committee established in 1974
- The first version of the Code of Ethics was published in 1980 in response to WHA 28.72



Professor Jean-Pierre Soulier
Inaugural Chair of Ethics Committee

WHA Resolution 28.72 May 1975



URGES Member States:

1. To promote the development of national blood services based on Voluntary Non Remunerated Blood Donation (VNRBD).
2. To enact legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products.

REQUESTS the Director General

2. To assist in establishing co-operation between countries to secure the adequate supply of blood products based on voluntary donations.
3. To further study the practice of commercial plasmapheresis including the health hazards and ethical implications, particularly in developing countries.

Code of Ethics for Blood Donation & Transfusion



- ISBT founded in 1935
- Ethics Committee established in 1974
- First version of the Code of Ethics was published in 1980 in response to WHA 28.72
- Code revised in 2000 and 2006 with minimal changes
- Further review initiated in 2014 and approved by the ISBT General Assembly in Copenhagen, 2017



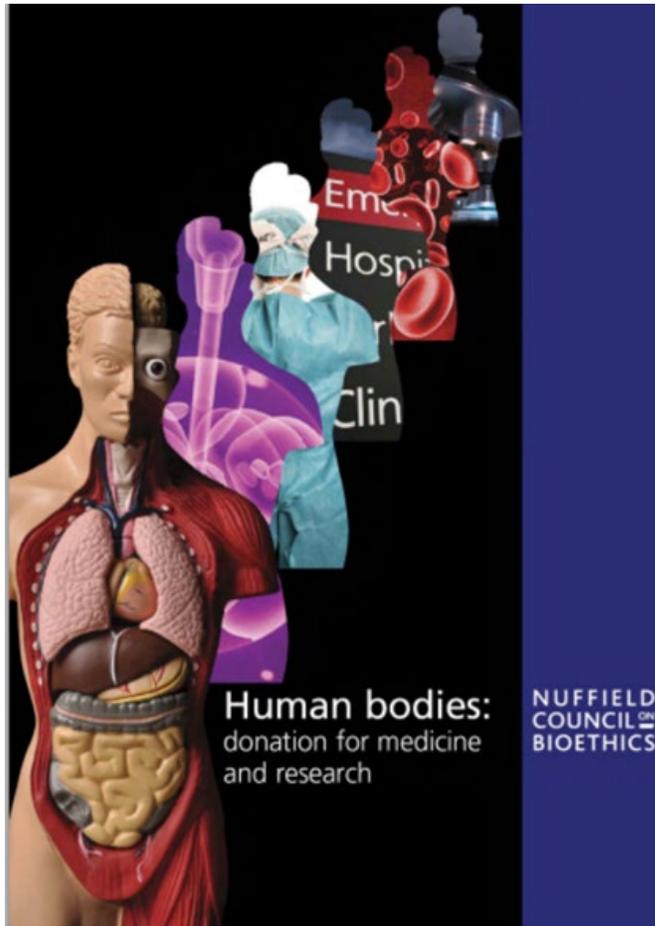
Professor Jean-Pierre Soulier
Inaugural Chair of Ethics Committee

Drivers for the Review of the Code in 2014



- It was almost 10 years since the 2005 review
- Increasing criticism of the Code
 - Failure to acknowledge the on-going, and increasing, commitment of Plasma Derived Medicinal Products (PDMP) derived from paid plasma
 - The argument that increasing use of donor incentives had blurred the distinction between VNRD and paid/compensated plasma
 - A belief that the Code suggested that access to commercial PDMPs should be restricted
- Requirement in the ISBT manual for Board members to abide by the Code

Nuffield Council on Bioethics



- Published in 2011 an extensive investigation on ethical issues relating to the human body and its donation for use in medicine and research.
- Included a specific analysis of the systems used for donating blood in the UK and the role that altruism should play in this.
- Defined a ladder for evaluating interventions used for recognition, reward and incentivisation of donation.

http://nuffieldbioethics.org/wp-content/uploads/2014/07/Donation_full_report.

The 2017 code



The 2017 Code of Ethics contains four sections:

1. Definitions
2. Ethical principles related to the patient
3. Ethical principles related to the donor
4. Stewardship

Statements within the Code



The 2017 Code of Ethics contains two types of statements related to each part.

1. A series of statements identifying the ethical principles that should underpin the way that we, as a body of professionals in the field of transfusion carry out our practice.

These ethical principles are within our control

Statements within the Code



2. A series of statement mainly directed at the health authorities and policy makers who set overall standards for blood service provision. These comprise the *Stewardship* section of the Code.

Professionals do not necessarily have control of these but do have an ability, and arguably a responsibility, to *advocate* for principles that are believed to be important.

Responsibilities of Transfusion Medicine Professionals



The responsibilities of Professionals involved in the field of transfusion medicine are aligned to the well acknowledged four principles of biomedical ethics:

- Autonomy
- Non-maleficence
- Beneficence
- Justice
- Dignity - specifically related to the donor

Ethics - 'the branch of knowledge that deals with moral principles'

<i>Dignity</i>	A human being has an innate right to be valued and receive ethical treatment.
<i>Autonomy</i>	The capacity of a rational individual to make an informed, un-coerced decision.
<i>Beneficence</i>	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.
<i>Non maleficence</i>	To “do no unnecessary or unreasonable harm.”
<i>Justice</i>	Concerned with the equitable distribution of benefits and burdens to individuals in social institutions, and how the rights of various individuals are realised.

Ethical Principles related to the Patient



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.

The Patient Autonomy



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

The Patient

Beneficence and Non-maleficence



- The patient has a right to be treated with dignity.
- Therapy must be given under the responsibility of a registered healthcare professional.
- Patients should be informed if information becomes available that indicates they have or may have been harmed by the transfusion.
- Information concerning the patient and their treatment should be managed in a confidential way.

The Patient Justice



- Patients should be treated equitably for the same health care condition.
- The patient should, within the constraints of the local health system receive the most appropriate blood product(s) that is (are) available.
- There should be no financial incentive to prescribe blood.

Ethical Principles related to the Donor



The *autonomy and dignity* of the donor, including potential donors, 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*

The Donor Autonomy



- The donor must expressly provide consent to the donation of blood. The consent must be informed and 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.
- Information provided by the donor and generated about the donor (i.e. test results) must be treated confidentially. The donor should be informed in advance of the release of any such information.

The Donor

Dignity and Non-maleficence



- Donor selection criteria must be applied to protect the health of recipients and donors. Donor must be made aware of their responsibility not to harm the recipient.
- Donors must be informed if they have, or may have been harmed or if results or information regarding their donation may have an impact on their health.
- The decision to administer any substance or medicine to a donor for any reason should take into account that there is no benefit to the donor.
- Anonymity between donor and recipient should be ensured except when both donor and recipient freely and expressly consent otherwise.

Stewardship



Advocacy Statements

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.

- There are a number of principles contained in the Code that fall within the Nuffield Council concept of Stewardship.
- Interestingly these are the main sources of criticism of the Code.
- They also comprise the 'advocacy' component of the Code identifying '*what we believe should be*' as opposed to '*what currently is*'.

The Code underlines ISBT's ongoing commitment to VNRBD



Consistent with the principles of the Oviedo Convention 1997 and World Health Assembly Resolution WHA28.72

ISBT affirms the importance of the principle of voluntary non-remunerated donation as the basis for the establishment and development of blood services.

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)

VNRBD

Dignity and Beneficence



- Blood donation should be seen as a community good and not as a commodity to meet other's ends.
- Blood donation should be voluntary and non remunerated. A donation is considered this if the person gives the 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.
- Any form of incentive 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.

VNRBD

Dignity and Beneficence



- Donation is a civic act for the benefit of others and contributes to social cohesion. There is no right to donate.
- 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.
- No coercion should be made on the donor to give blood.

VNRBD

Justice and Non-Maleficence



- 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.
- Wastage of blood should be avoided in order to safeguard the interests of all potential recipients and the donor.
- All matters related to donation of blood and its clinical use should be in compliance with appropriately defined and internationally accepted standards.

Commercialisation and Profit Motive



- The issue of commercialisation and avoidance of a profit motive is addressed but unlike the 2006 version it is restricted to *blood service* provision.
- The broader issue of commercialisation of products is addressed in the section on donor consent. Essentially this is permissive in the Code so long as the donor is properly informed that this might occur.
- This approach reflects the modern reality that product development and research are often associated with intellectual property rights and significant investment in research and development.

Summary



- The Code of Ethics is a living document that is relevant to transfusion medicine professionals and thus members of the Society and should be easily accessible.
- It also relates to donors and patients.
- The stewardship section relates to the activities of Blood Services to assure the needs of patients using an ethical framework.
- Ongoing review is needed to ensure that the Code remains relevant and that it responds to the changing world of transfusion medicine and science.

Acknowledgments



Peter Flanagan – Chair of the ISBT Standing committee on Ethics

Members of the committee:

Justina Ansah, Ghana, Roger Dodd, USA

Che Kit Lin, Hong Kong, Neelam Marwaha,

India, Guy Rautmann, France

Hasan Abbas Zaheer, Pakistan

ISBT

ISBT

International Society
of Blood Transfusion

CODE OF ETHICS RELATING TO TRANSFUSION MEDICINE

PURPOSE

This code defines the ethical and professional principles that the International Society of Blood Transfusion (ISBT) 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.

