

ISBT Code of Ethics

IL FUTURO DELLA TRASFUSIONE
TRA MEDICINA RIGENERATIVA ED
ETICA

Sabato 24 novembre, Varese

Karin Magnussen

What is Ethics?

- **Ethics are ground rules of good behaviour**
- **Shared principles promoting fairness in social interactions**

Purpose

- **This Code defines**
 - the ethical and professional principles that should underpin the establishment and activities of a Blood Service
 - and identifies ethical and professional standards for practitioners active in the field

Key changes in the current Code

- The Code of Ethics now contains two types of statements
- A series of statements identifying the ethical principles that should underpin the way professionals work
 - These principles are within control and aim to ensure the highest standards of professional service to both donors and patients
- The second series of statements are mainly directed at the health authorities and policy makers who set overall standards for blood service provision
 - Professionals do not necessarily have control of these but do have an ability, and indeed a responsibility, to advocate for principles believed to be important. These latter 'advocacy principles are included in a new section on 'stewardship'

ISBT Code of Ethics

- It outlines the responsibilities of *Professionals* involved in the field of transfusion medicine to *donors* and to *patients*
- It is aligned to the well acknowledged four principles of biomedical ethics:
 - *autonomy, non-maleficence, beneficence, and justice*
- Another principle, *dignity*, covering all four principles, specifically applies to *donors*
- The Code also includes a series of statements directed to *health authorities* that relate to the stewardship of the blood supply

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

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
<i>Beneficence</i>	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 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

Autonomy

- **Informed consent must be obtained from the recipient**
- **If that is no possible the transfusion must be in the best interest of the patient**

Beneficence and non-maleficence

- 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
- Transfusion therapy must be given under the overall responsibility of a registered healthcare Professional who is competent to do so
- Patients should be informed if information becomes available following a transfusion that indicates they have, or may have been, harmed by the transfusion
- Information concerning the patient and the treatment that they receive should be managed in a confidential manner

Justice

- 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
- The patient should, within the constraints of the local health system, receive the most appropriate blood products that 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
- **There should be no financial incentive to prescribe *blood***

Ethical Principles Relating to Donors

- 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

Autonomy

- The *donor* must expressly provide consent to the donation of *blood*. The consent **must** be informed.
 - 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 test results **should** be treated confidentially. The *Donor* **should** be informed in advance of the release of any such information

Dignity and non-maleficence

- 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
- *Donors* **should** be informed if they have, or may have been harmed or whether any results or information regarding their donation can have an impact on their health

Dignity and non-maleficence

- The decision to administer any substance or medicine to a *donor* 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
- Anonymity between *donor* and recipient should be ensured except when both *donor* and recipient freely and expressly consent otherwise

Dignity and beneficence

- 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
 - The establishment and running of a blood service should be based upon not-for-profit principles
- Donation is a civic act for the benefit of others and contributes to social cohesion
 - There is no right to donate

Dignity and beneficence

- Blood donor selection should be based on current, accepted and regularly reviewed scientific data. The ability to donate should not be unnecessarily restricted
 - Blood donation criteria should not be justified on the basis of gender, race, nationality, religion, sexual orientation or social class
- Neither donor nor potential recipient has the right to require that any such discrimination be practiced
- No coercion should be made on the donor to give blood

Dignity and beneficence

- *Blood donation should be voluntary and non-remunerated*
 - The donor 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 needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with VNRBD

Dignity and beneficence

- 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 recipient

Justice

- 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*

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

Conclusion

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

Grazie per l'attenzione

