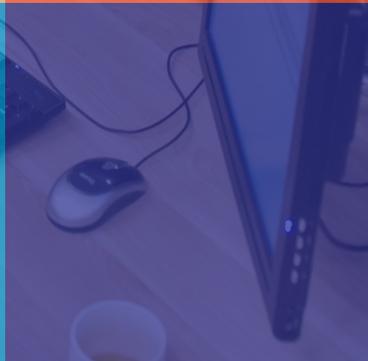




ETHICAL CHARTER

Eurotransplant International Foundation



Mission statement Eurotransplant

The Mission of Eurotransplant is formulated as follows:

To be a service organization for transplant candidates through the collaborating transplant programs within the organization.

Its aims are:

- To achieve an optimal use of available donor organs;
- To secure a transparent and objective allocation system, based upon medical and ethical criteria;
- To assess the importance of factors which have the greatest influence on waiting list mortality and transplant results;
- To support donor procurement to increase the supply of donor organs;
- To further the results of transplantation through scientific research and to publish and present these results;
- The promotion, support and coordination of organ donation and transplantation in the broadest sense of the term.

These aims are propagated by the Board of Management, General Assembly and the Advisory Committees and Councils of Eurotransplant and implemented in close collaboration with its executive directors.

The Eurotransplant Ethics Committee (ETEC)

Eurotransplant has established an Ethics Committee (EETEC) that is responsible for considering current ethical and legal issues in organ donation, allocation and transplantation that have a bearing on the day-to-day practice and collaboration within the Eurotransplant organization. The ETEC will assist the organization by taking agreed positions (Position Statements) on these issues and advising the Board of Management on their implementation. It should also look to identify future issues to enable Eurotransplant to develop a well defined position before presenting the issue to the wider society.

Responsibilities

The role of ETEC:

- Consideration of current and future ethical (and related legal) issues in organ donation, allocation and transplantation that impact the activities of the Eurotransplant organization;
- Setting ethical standards for collaboration in the fields of organ donation, allocation and transplantation that takes place under the responsibility of Eurotransplant within the community of associated member centers;
- Formulation of Position Statements and recommendations that reflect the views and aims of the Eurotransplant organization and that have been ratified by the Board of Management.
- Review and revise existing Position Statements and Recommendations on a regular basis;
- Horizon scanning of potential ethical issues in organ donation, allocation and transplantation;
- Dissemination of Position Statements through publication on the Eurotransplant website;
- Organize Ethic sessions and seminars as a tool for education within the Eurotransplant community.

General background on organ donation and transplantation: ethical aspects

Over the past decades, transplantation of human organs has developed into a worldwide practice which has prolonged the life and enhanced the quality of a great number of patients with organ failure. Because of its success and continuous improvement, there has been a steady increase in the demand for transplantable organs that has continuously outstripped the actual supply of organs, despite a substantial expansion in organ donation from deceased persons as well as from living persons.

In general the framework for the retrieval, allocation and transplantation of human organs for therapeutic reasons should be governed by principles and regulations that assure an orderly, ethical and acceptable handling and distribution of these scarce resources. Shared professional medical guidelines and standards, as well as ethical and legal standards should underpin these practices. Since Eurotransplant operates as a supranational organ exchange organization, building on voluntary collaboration between a (growing) number of European States, it is self evident that its policies shall also take into account the standards and regulations laid down in domestic legislation of these countries. Additionally, the international cross-border exchange of organs within Eurotransplant, and between Eurotransplant and other countries, makes it necessary that its policies comply with internationally accepted ethical standards, as laid out in the (revised) WHO

Guiding Principles¹, the Additional Protocol to the European Biomedicine Convention², the European Directive³, and the Istanbul Declaration on Organ Trafficking⁴. These documents stipulate that organ donation and transplantation be governed by ethical standards and principles of human dignity, respect, fairness, and non-commercialism.

The enduring shortage of available organs has not only stimulated countries (within Eurotransplant) to adopt procedures and measures to increase their supply of transplantable organs, but has unfortunately also stimulated commercial traffic in organs, particularly from living donors who are mostly unrelated to the recipients. In recent times the evidence of such commerce, facilitated by the trafficking of human beings, has become more visible. In addition, the development of international communication and growth of travel has prompted many patients to go abroad to obtain a transplant. This has been facilitated by medical centers in a number of countries that advertise their ability to perform commercial transplants using unrelated paid donors. Although the social and economic situation in Europe is not easily comparable to that of some (developing) countries that have become a hub of organ trade, there is no guarantee that organ commercialism will not and could not occur in Europe or involve patients and donors from the Eurotransplant region. Eurotransplant therefore must take a stand against these illegal practices.

Position statements of the ETEC (general and specific)

Core principles

In all deliberations and recommendations of the Ethics Committee the need and well-being of the patient (as well as the donor) is a key focus.

On donation and allocation of organs:

- Eurotransplant is committed to supporting its member countries' objective to develop donation from deceased persons to its maximum therapeutic potential, taking into account aspects of safety and quality, as well as ethical acceptance of procedures for retrieval.
- Eurotransplant will handle only human organs that have been procured and in accordance with (ethical) principles laid down in international regulations and conventions (such as European Bioethics Convention, WHO guidelines, EU Directive).
- Eurotransplant shall ensure the traceability of the organs by its organization.
- Organs handled and allocated by Eurotransplant must have been obtained on the basis of proper and valid consent, in accordance with legislation in the member state.
- Organs handled and allocated by Eurotransplant shall originate from donors for whom death has been determined according to nationally approved medical and legal standards.
- Eurotransplant shall ensure that the allocation of organs under its responsibility be guided by clinical and ethical criteria, and allocation rules that are defined by appropriately constituted committees, based on principles of fairness, equity and transparency, and in accordance with regulations of the member countries.
- Eurotransplant will accept patients on its waiting list for transplantation according to accepted and transparent medical criteria (indication, need, urgency). Allocation of available organs will be based primarily on clinical criteria (need, urgency, match, other aspects related to both the donor organ and the recipient) and accrued waiting time, taking into account ethical principles, and without regard for personal, social or financial background.
- As Eurotransplant operates on the basis of international cross-border collaboration and exchange of organs, its procedures for allocation across participating countries must take into account the principle of solidarity within each country (to be implemented through a mutually agreed balancing system).

¹ WHO Guiding Principles on human cell, tissue and organ transplantation, revised version of 26 May 2008 (EB123/5)

² Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin. Strasbourg, 24.I.2002

³ Directive of the European Parliament and Council on standards of quality and safety of human organs intended for transplantation (COM)

⁴ The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, TTS and International Society of Nephrology, May 2, 2008.

On confidentiality and data protection:

- Eurotransplant will respect the anonymity of donors and recipients and protect the confidentiality of personal data stored in its databases.

On prohibition of organ commercialism:

- Eurotransplant declares its opposition to commercialization of human organs or any body part (i.e. any financial gain or benefit resulting from selling or buying of organs by donors or recipients, or by physicians acting as brokers or solicitors). It is also opposed to any practice of transplant trafficking or transplant tourism that exploits and endangers donors and/or recipients, making use of coercion, deception or payment/financial inducement (in agreement with the Istanbul Declaration).
- No transplant surgeon, physician, team or hospital associated or collaborating with Eurotransplant shall be involved in any way (directly or indirectly) in the buying and/or selling of organs, or in knowingly facilitating organ tourism or trafficking.

On transplant-related research:

- All scientific and clinical research related to human organ donation and transplantation involving human beings (ic patients, donors or healthy volunteers), that is conducted either under the responsibility of Eurotransplant and/or undertaken by one or more associated member centers, must conform with the current Helsinki ethical standards.
- Local Institutional Review Board approval and/or the opinion of the ETEC must be sought and granted.
- Ethical criteria for this research shall include: respect for personal dignity; no unreasonable risk to the health and safety of the person; full informed consent (particularly in case of incompetent or vulnerable subjects); freedom to withdraw; no reimbursement that acts as an incentive.
- Eurotransplant shall contribute to the continuing improvement of transplant procedures and their short- and long-term outcomes by facilitating and promoting data collection, analysis and evaluation (by promoting, facilitating and/or setting up transplant registries).
- All organs, when not used/usable for transplantation, are handled with respect and care, and either used for research (as allowed by the national legislation of the donor country of origin), or discarded and disposed of, according to agreed standards and procedures.