



COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Committee of Ministers
Comité des Ministres

**Recommendation Rec(2006)15
of the Committee of Ministers to member states
on the background, functions and responsibilities of a National Transplant Organisation (NTO)**

*(Adopted by the Committee of Ministers on 8 November 2006
at the 979th meeting of the Ministers' Deputies)*

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, in particular by the adoption of common rules in the public health field;

Bearing in mind the Convention on Human Rights and Biomedicine (ETS No. 164), in particular its Articles 19 and 20, and Article 3 of the Additional Protocol to the Convention on Human Rights and Biomedicine on Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Recalling its Recommendations to member states, Rec(2001)5 on the management of organ transplant waiting lists and waiting times, and Rec(2004)7 on organ trafficking, and recalling its Resolution (78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances;

Considering that:

- organ transplantation is a well-established, life saving, and effective treatment. It may be the only treatment available for some forms of end stage organ failure and is the most clinically effective and cost effective treatment for chronic renal failure; tissue and cell transplantation may be life saving or life enhancing;
- organ transplantation, and sometimes tissue transplantation, is severely limited by the availability of organs for transplantation;
- a properly established and managed transplantation system is essential to maximise the rate of organ and tissue donation and provide equitable access to transplantation services for patients by guaranteeing the allocation of organs and tissues following rules which are transparent, objective and justified according to medical criteria, and by guaranteeing traceability and accountability,

Recommends that the governments of member states:

- i. set up a comprehensive national transplantation system (NTS) for the authorisation,¹ organisation and monitoring of organ, tissue, and cell donation and transplantation, taking into account the differences in the procedures of organ, tissue and cell donation and transplantation in member states;
- ii. ensure that the NTS has a statutory basis which clearly sets out the structure of the system, its powers and responsibilities. It is preferable to have a single public body (a national transplant organisation (NTO)) which is officially recognised, and non-profit making with overall responsibility for donation, allocation, traceability and accountability. However, a combination of local, regional, national and/or international bodies may work together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency;

¹ The term "authorisation" is meant to include the following three functions: accreditation, licensing, and designation.

- iii. ensure that the NTS has competencies and mechanisms to organise and oversee the whole process of transplantation including: public education on transplantation; organ (and tissue) donation and retrieval; national transplant recipient waiting lists; organ (and tissue) allocation; organ (and tissue) transportation including international exchanges; authorisation of organ transplant teams or institutions; the traceability of organs and tissues and monitoring of outcomes of transplantation and donations from living donors. Other NTS competencies may include research into transplantation and responsibility for identifying and reporting to the relevant authorities any breaches of the national transplantation law;
- iv. implement the above recommendations taking into account the appendix to this recommendation.

*Appendix to Recommendation Rec(2006)15
of the Committee of Ministers to member states
on the background, functions and responsibilities of a National Transplant Organisation (NTO)*

Transplantation is a complex process requiring a large number of functions to be managed effectively. Ideally, these functions should all be the responsibility of a single national transplant organisation (NTO), particularly with regard to organ transplantation. However, if the national transplantation system (NTS) integrates more than one structure, it is critical to ensure that the functions performed by each structure are appropriate, and complement those of the other transplant structures. The following allocation of functions is consistent with internationally recognised practice.

1. The essential functions of an NTO (with its advisory committees) are the following:
 - running a central office which is operational 24 hours a day, 7 days a week, with which all donors have to be registered and which manages national or international organ allocation;
 - ensuring that all relevant donor data, including screening results, are collected and communicated to the recipient's transplant team;
 - managing specific national waiting lists for organs, and, if applicable, for tissues, on the basis of agreed and transparent national admission criteria, containing sufficient up-to-date data on the recipient to ensure optimal matching;
 - ensuring that all donated organs are allocated to the most appropriate recipient in compliance with nationally agreed and transparent allocation rules, to ensure as far as possible equal access to transplantation for all patients who could benefit from a transplant;
 - ensuring that arrangements are in place for the safe and rapid transport of organs from the donor's hospital to the recipient's hospital;
 - ensuring the maintenance of a transplant database of all donors and recipients, including follow-up data on living donors and recipients, to ensure traceability and to audit the outcome of transplant programmes;
 - taking responsibility for running a transplant quality assurance system consistent with internationally recognised standards;
 - providing accurate information to professionals on organ and tissue donation and the outcomes of transplantation as well as being responsible for professional education about transplantation and raising the awareness of the public about organ and tissue donation and transplantation;
 - ensuring complete transparency of national transplant procedures and processes in order to maintain or improve public and patient trust in the NTS;
 - taking up national/international responsibility for tissue donation and transplantation.
2. The following functions should ideally be the responsibility of the NTO, or its advisory committees; alternatively they could be taken by other bodies in co-operation with the NTO:
 - taking responsibility for the recruitment, training and appointment of donor transplant co-ordinators in all major hospitals likely to provide organ donors;
 - taking responsibility for the co-ordination and management of donors and/or other transplant co-ordinators;

- conducting a regional/national potential donor audit to assess the total potential donor “pool” and identify reasons for non-donation;
- managing national organ donor/non-donor registers;
- reviewing donor screening methods and requirements to ensure compatibility with international standards and adapting them to any specific local requirements, if applicable;
- determining specific information requirements for organ and tissue donors;
- setting standards for donor management;
- setting standards for organ retrieval procedures, in particular multi-organ retrieval operations, in order to maximise organ quality and preservation;
- organising and co-ordinating organ donation and retrieval procedures;
- setting standards for organ and tissue packaging, labelling and transportation;
- organising the transport of organs and tissues from the donor’s hospital to the recipient’s hospital or tissue bank;
- setting criteria for the admission of patients to national organ or tissue-specific waiting lists;
- reviewing and analysing national transplant waiting lists, that is, waiting times according to demography, geography, etc., as a basis for recommending changes to allocations rules in order to ensure optimum allocation of organs;
- managing and analysing transplant data through the donation process, including an analysis of allocation, to ensure that the rules are properly applied and to prevent organ trafficking;
- taking responsibility for offering organs to other NTOs if a compatible recipient is not available;
- maintaining registers of all donors, including living donors, and all transplant recipients and/or designing and operating an integrated national transplant information system;
- in cases where a disease is transmitted to a recipient, identifying all other recipients of organs or tissues from that same donor, and/or allowing the retrieval and disposal of any unused organs or tissues;
- offering advice on the types of transplant that should be paid for by national health systems and any that may be allowed in the private sector;
- accrediting transplant teams and/or institutions allowed to perform organ and tissue transplants;
- inspecting and accrediting tissue banks in line with international standards, such as the standards set by the Council of Europe Guide to safety and quality assurance in organs, tissues and cells and the requirements set by the European Union Directive 2004/23/EC on setting standards for quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
- managing and overseeing haemopoietic progenitor cell (HPC) transplants, including the importing of HPC cells;
- collecting data on outcomes and follow-up from transplant teams and units;
- auditing transplant procedures and outcomes to allow constant improvements in the safety and quality of organ transplantation;
- submitting outcome data to international transplant registers;
- organising and managing public relations and communication strategies on national transplantation issues;
- identifying patients registered on more than one national waiting list, and exposing possible cases of organ trafficking;
- setting standards for the screening and preparation of potential living donors;
- authorising living donor transplants, if foreseen by the NTS.

3. In view of a potential conflict of interest, the following function should not be the responsibility of the NTO but of a separate body, not related to a transplant organisation:

- setting the criteria to determine death either according to brain and brain stem failure or after cardiorespiratory failure to allow heartbeating and non-heartbeating organ donation, if foreseen by national law.

4. Member states wishing to collaborate within the framework of a supranational organisation should consider that the NTO should remain responsible for deciding on the functions to be allocated to an international body.