

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Recommendation Rec(2004)19
of the Committee of Ministers to member states on criteria for the authorization of organ
transplantation facilities

*(Adopted by the Committee of Ministers on 15 December 2004,
at the 909th meeting of the Minister's 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 *inter alia* by the adoption of common action in the health field;

Taking into account Resolution N° (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances, the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987); Articles 19 and 20 of the Convention of Human Rights and Biomedicine, and Articles 3 and 4 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin;

Considering:

- organ transplantation is a well-established, life-saving, and effective treatment: a successful organ transplantation may be the only treatment available for some forms of end stage organ failure and it's the most clinically and cost effective treatment for chronic renal failure;
- organ exchange and circulation of recipients among member states is becoming a more frequent phenomenon, and that a minimum common standard should be guaranteed to the citizens;
- member states should therefore provide high-quality transplant services for the benefit of their citizens. Considering the limited organ supply, all necessary steps should be taken to make sure all available organs are properly safeguarded and used so as to maximize the benefit to patients;
- the highest professional standards are to be maintained in the area of organ transplantation;

Recommends that the governments of member states take all necessary measures to ensure the following:

1. An appropriate mechanism for the authorization¹ of health care facilities carrying out organ transplantations² should be set up. In order to obtain authorization these facilities should meet the following criteria;
 - feasibility of programme, based on clinical need assessment and a documented estimate of organ supply, to ensure that projected activity levels are sufficient to maintain clinical expertise and programme quality;

- standards of vocational training of team members, and infrastructural conditions relating to availability of beds, intensive care facilities, and diagnostic and therapeutic back-up services (radiology, microbiology, immunology services, etc.), and to care provided by nursing, physiotherapy, social services and related medical professionals.
- 2. Medical professionals forming part of an organ transplant team should be properly qualified and their previous training in the field of transplantation should be documented and personalized.
- 3. A quality-management system should be put in place to evaluate performance against established national and/or international standards as applicable, and to ensure the quality of the process of organ procurement and transplantation, following the principles described in the Council of Europe's *Guide to safety and quality assurance for organs, tissues and cells*.
- 4. Authorisations should be regularly reviewed against agreed quality criteria and standards, as well as against audit results.
- 5. Outcome results for each type of transplant should be within the margins of international registers, at an equivalent degree of complexity of patients. In order to guarantee clinical results and cost-effective performance, minimal yearly activity standards shall be established in order to maintain an active programme.
- 6. These minimal activity standards, required to keep each kind of transplant programme, should be related to the mean number of cadaveric organs available to the transplant team in recent years.
- 7. Any transplant centre, which, after several warnings, continues to fail to meet activity or outcome criteria, may have its authorization withdrawn.
- 8. No new transplant center may be authorized if there are not enough organs available to enable a new center to reach the required standards.
- 9. Any new transplant center should be authorized, accredited or licensed on the basis of agreed criteria and initially should be limited in time. If, within an agreed timescale, the new center does not achieve the required standards, authorization shall be withdrawn.

Note ¹ For the purpose of this Recommendation, the term "authorization" refers to any appropriate mechanism for designating, authorizing, accrediting or licensing health care facilities carrying out organ transplantations.

Note ² This Recommendation refers to the facilities where organs are being "implanted".