# COUNCIL OF EUROPE
## COMMITTEE OF MINISTERS

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RECOMMENDATION No. R (97) 16

**OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON LIVER TRANSPLANTATION FROM LIVING RELATED DONORS**

*(Adopted by the Committee of Ministers on 30 September 1997 at the 602nd 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, *inter alia*, by the adoption of common action in the health field;

Considering that liver donations by living related donors saves the lives of children;

Bearing in mind that, in liver transplantation with living related donors, the ethical principles concerning organ transplantation as set out in Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances, and agreed at the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987), should be respected under all circumstances and that fully informed consent is required from both the donor and the recipient;

Mindful of the provisions of Articles 19, 20 and 21 of the Convention on Human Rights and Biomedicine;

Taking account of World Health Organisation Resolution WHA 42.5 condemning the purchase and sale of organs of human origin,

Recommends that governments of member states conform to the rules set out in the appendix to this recommendation in carrying out living related liver transplantation (LRLT).

Appendix to Recommendation No. R (97) 16

i. LRLT should be considered only when there is a shortage of cadaver organs, that is when alternatives that do not carry the risks incurred by a living donor have been exhausted.

On the evidence currently available, LRLT should be considered only for children and should not be recommended for adults nor in an emergency situation such as fulminant liver failure.

ii. Potential recipients of LRLT should have been previously assessed as suitable for cadaveric transplant and, if considered suitable for LRLT, should still be retained on the waiting list for the cadaveric programme in case a suitable

liver becomes available. If it is unlikely that a suitable cadaveric liver will become available within the required timescale, then the patient and relatives should be informed of the possibility of LRLT.

iii. The potential risks, including morbidity and mortality, arising from LRLT as well as its benefits should be explained to the potential recipient. The consent of the donor should be obtained only after a full explanation of the risks of LRLT and an assessment of the donor's suitability by a third party, that is a "donor advocate" independent of the transplant team.

Fully informed consent should also be obtained from the recipient (or recipient's representative).

iv. Minors and adults not having the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons should not be considered as donors.

v. Centres performing LRLT should have available a body of medical and non-medical professionals independent of the team performing the transplant to provide guidance on ethical issues relating to LRLT. A mechanism for independent assessment of the donor should be available as a minimum requirement to ensure that he/she is not under pressure to consent.

vi. LRLT should be performed only in centres with extensive experience of all aspects of liver surgery, notably liver splitting techniques, and adult and paediatric liver transplantation, and within the framework of a quality assurance programme.

Centres should perform LRLT procedures only with the approval of an appropriate transplant regulatory body. The procedures should be registered with the regulatory authority and the results monitored by a recognised method of peer review (until the results are considered acceptable).

vii. Living related donors should not participate in medical experiments unless their objective is to evaluate the LRLT.