



COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Committee of Ministers
Comité des Ministres

Resolution CM/Res(2008)4 on adult-to-adult living donor liver transplantation

*(Adopted by the Committee of Ministers on 12 March 2008
at the 1021st meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the elaboration of a European Pharmacopoeia,¹

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 public health field;

Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine – ETS No. 164), and in particular Article 19 (General rule) and Article 20 (Protection of persons not able to consent to organ removal) thereof;

Having regard also to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), and, in particular, Chapter III (Organ and tissue removal from living persons);

Recalling its Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances;

Recalling its Recommendation Rec(2001)5 to member states on the management of organ transplant waiting lists and waiting times;

Recalling its Recommendation Rec(2004)7 to member states on organ trafficking;

Recognising that, in facilitating the transplantation of organs in the interest of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ procurement, exchange and allocation activities;

Considering that organ transplantation is a well-established, life-saving, and effective treatment and may be the only treatment available for some forms of end-stage organ failure;

Aware of the fact that tissue and cell transplantation may be life saving or life enhancing;

Concerned by the universal shortage of organs for transplantation;

Considering that adult-to-adult living donor liver transplantation (Domino liver transplantation, i.e. transplantation into a recipient whose own organ was respected and transplanted into another recipient, is excluded from the scope of this resolution) may be envisaged when suitable organs from deceased donors are not available, provided that all safeguards are implemented in order to guarantee the freedom and safety of the donor and a successful transplant in the recipient;

¹ States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey and United Kingdom.

Convinced also that adult-to-adult living donor liver transplantation is an effective treatment for end-stage liver disease, with the potential benefit of reducing mortality of patients awaiting a transplantation;

Conscious of the risks that living donor liver transplantation may have for the donor and of the need to ensure that all measures are taken to safeguard the donor's health;

Recalling that no organ removal may be carried out on a person who does not have the capacity to consent;

Recommends to member states the following:

1. to instruct the organisation responsible for accrediting transplantation programmes and regulating the allocation of organs to address explicitly the issue of adult-to-adult living donor liver transplantation and establish transplantation programmes accredited to perform this type of transplantation;
2. to ensure that adult-to-adult living donor liver transplantation programmes adhere to the following minimum requirements:
 - a. substantial experience in liver surgery and liver transplantation;
 - b. an active liver-transplantation programme;
 - c. significant mortality in the waiting list;
 - d. a multidisciplinary team experienced in routine and complex liver surgery, covering all operative aspects (pre-operative, peri-operative and post-operative);
3. to ensure that the indications for adult-to-adult living donor liver transplantation are recognised indications for deceased donor liver transplantation;
4. to ensure that the organisation responsible for the allocation of organs and accreditation of transplantation programmes establishes clear conditions under which adult-to-adult living donor liver transplantation is ethically acceptable, namely:
 - a. adult-to-adult living donor liver transplantation is only to be performed within authorised/licensed programmes with ongoing feedback;
 - b. the donor and the recipient have a close personal relationship as required and defined by law;
 - c. each single procedure should be approved on a case-by-case basis;
 - d. the motive to donate is solely altruistic. Any financial gain or comparable advantage in connection with the donation is considered illegal;
 - e. the donor has been given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks. The donor has also been informed of the rights and the safeguards prescribed by law for his or her protection, in particular of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ removal or subsequent transplantation procedures. Finally, the donor is provided with comprehensive information on:
 - i. the alternatives to adult-to-adult living donor liver transplantation;
 - ii. the previous experience of the centre where the procedure will be carried out;
 - iii. the risks of morbidity and mortality of the procedure for the donor and the recipient;
 - iv. the likely long-term outcome for the recipient;
 - f. the living donor has given free, informed and specific consent either in written form or before an official body; the donor may freely withdraw consent at any time;

- g. the donor has been properly screened to identify any physical or psychological contra-indication; the removal may not be carried out if there is a serious risk to the life or health of the donor;
5. to ensure immediate access to the emergency waiting list for organs from deceased donors in case of failure of the remnant liver in the donor or graft failure in the recipient and that specific rules for non-residents apply according to national regulations;
6. to ensure that the necessary conditions and provisions are in place for long-term medical follow up of both donor and recipient, including the monitoring of the short- and long-term effects of transplantation on the health of donors, by the establishment of national registries;
7. to guarantee equitable access to liver transplantation services for all patients in need of a liver transplant, regardless of personal financial means;
8. to ensure that all costs related to the operations and follow-up of donor and recipient are covered, according to the competent organisation's own procedures;
9. to provide for a system of fair compensation for any person who suffered undue damage resulting from transplantation procedures, according to the conditions and procedures prescribed by law.