

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

Recommendation Rec(2003)12 of the Committee of Ministers to member states on organ donor registers

*(Adopted by the Committee of Ministers on 19 June 2003
at the 844th 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 regulations in the 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 (the Convention on Human Rights and Biomedicine) (ETS No.164);

Having regard to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Bearing in mind that:

- the Protocol concerning the Transplantation of Organ and Tissues of Human Origin requires member states to have a legally recognised system specifying the conditions under which removal of organs or tissues is authorised;
- by virtue of Article 8 of the said protocol, member states should take appropriate measures to inform the public, namely about matters relating to consent or authorisation with regard to the removal of organs or tissues from deceased persons;
- Article 17 of the said protocol prohibits the removal of any organ or tissue unless the consent or authorisation required by national law has been obtained by the person proposing to remove the organ or tissue;

Recalling the general principles relating to data protection of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108),

Recommends to governments of member states to conform with the principles contained in the appendix to this recommendation as regards organ donor registries:

Appendix to Recommendation Rec(2003)12

1. Careful consideration should be given to the need for, and purpose of, an organ donor register.
2. In those member states with a legal framework for organ donation which assumes people are willing to donate their organs or tissues unless they have registered their refusal (opt-out system), states must provide an effective means for people to register their decision. A national register can be an effective means of recording such decisions.
3. For member states in which consent to donation is actively sought from the donor and/or those close to them prior to organ donation (opt-in system), an organ donor register may also fulfil important functions:
 - as a means of registering the wishes of people willing to donate their organs;
 - as a means of improving the efficiency of the organ and tissue donation process by making those wishes available rapidly after the death of a potential donor has been confirmed;

- as a means of publicising organ donation, and of involving people and organisations in realising the benefits of organ donations for themselves and for others in society;

4. Consideration should be given to the primary function of the organ donor register. Organ donor registers may:

- be opt-out only;
- be opt-in only;
- register both choices, or even a third choice, such as “ask my relatives”;
- allow simply a general agreement to donate organs and/or tissues;
- allow wishes about the donation of particular organs and/or tissues to be specified;
- allow registration of wishes with respect to other sensitive procedures, such as post-mortem examinations or the donation of organs/tissue for medical research.

5. Organ donor registers should ensure, that:

- people wishing to register their wishes can do so easily and reliably;
- people can, if they wish, specify organs and tissues they do/do not wish to donate;
- people can revoke their entry at any time;
- all information on people who die is removed from the organ donor registry.

6. If the organ donor register is intended to facilitate organ donation it must:

- have details of a high proportion of potential donors/non-donors. If enquiries about potential donors give no results, health professionals will consider it a waste of time trying to access the register;
- enable easy and rapid twenty-four hour access by health professionals needing information about a potential donor.

7. Careful consideration should be given to the costs and benefits of setting up and maintaining an organ donor register:

- member states operating an opt-out system should, as a minimum, have a central register for those who do not wish to donate organs or tissues or any particular organ or tissue;
- a centrally-run information technology-based organ donor register offers the greatest flexibility in terms of content, updating and rapidity of access, but data security has to be ensured;
- everyone should be able to register their wishes;
- registration must be easy, preferably by both written and/or electronic means;
- written confirmation should be sent to all who register;
- people should have a simple means of checking and amending their entry
- specified healthcare professionals such as intensive care staff and/or transplant co-ordinators must have twenty-four-hours-a-day access to check the wishes of potential donors by phone, fax or electronically. Such checks should normally be made only after the death of a potential donor;
- checking the register could be made mandatory as a condition of donation.

8. Member states with organ donor registers should consider whether their register is designed and operated in a way which best meets the needs of their population and transplant service. Those member states which have an organ donor register are advised to consider the purposes and the likely advantages and disadvantages before establishing a new organ donor register.