



Opinion 227 (2001)¹

Draft additional Protocol to the Convention on Human Rights and Biomedicine, concerning transplantation of organs and tissues of human origin

Parliamentary Assembly

1. The Parliamentary Assembly welcomes the draft additional protocol to the Convention on Human Rights and Biomedicine, concerning transplantation of organs and tissues of human origin, which will provide a European legislative framework for the principles and practices that must prevail in this field.
2. The Assembly notes with satisfaction that the draft protocol reaffirms the principles that inspire the Convention on Human Rights and Biomedicine: primacy of the human being, equitable access to health care, freely given and informed consent, and prohibition of financial gain.
3. The Assembly notes with interest that the draft protocol leaves five matters concerning arrangements for its implementation or enforcement to the discretion of states:
 - 3.1. the organisation of a transplantation system (Article 3);
 - 3.2. the definition of appropriate relationships between recipients and live donors (Article 9);
 - 3.3. the removal of regenerative tissue from live donors who do not have the capacity to consent (Article 13);
 - 3.4. the certification of death (Article 15);
 - 3.5. the consent of a deceased person to removal and authorisation of removal (Article 16).
4. Nevertheless, the Assembly wishes to see strengthened the protection of live donors and the prevention and repression of illegal trafficking in organs and tissues, notably through the intermediary of adoption.
5. Consequently, the Assembly recommends that the Committee of Ministers adopt the draft additional protocol to the Convention on Human Rights and Biomedicine, concerning transplantation of organs and tissues of human origin, subject to the modifications proposed in the following paragraphs.
6. In Article 2 of the draft protocol, at the end of paragraph 1, add the following words: "... including those which have been subject to modification".
7. In Article 3 of the draft protocol, after the third paragraph, add the following new paragraph: "The provision of organs even in shortage situations must be based exclusively on individual health benefits for the patients in question."

1. Assembly debate on 25 April 2001 (13th Sitting) (see [Doc. 8997](#), report of the Social, Health and Family Affairs Committee, rapporteur: Mr Mattéi; [Doc. 9033](#), opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Asciak; and [Doc. 9059](#), opinion of the Committee on Culture, Science and Education, rapporteur: Mr Wodarg). Text adopted by the Assembly on 25 April 2001 (13th Sitting).



8. In Article 7 of the draft protocol, after the existing paragraph, add the following new paragraph: - "The institutions and persons responsible in the transplantation system must at all times uphold the protection and the rights of donors as well as of their families. Institutional interests must be relegated to a position of secondary importance in connection with obtaining and distributing organs."

9. As regards the principle of prohibiting the removal of organs from living persons, while allowing for certain strictly limited exceptions, the Assembly proposes the redrafting of Articles 8 and 9 to read as follows: Article 8: "Removal of organs or tissues from a living person shall be prohibited, save in exceptional circumstances as described in Article 9." Article 9: "Removal of organs or tissues from a living donor may be carried out solely for the therapeutic benefit of the recipient, provided that there is no alternative therapeutic method of comparable effectiveness and there are personal ties between the donor and the recipient as defined by law, and with the approval of an appropriate independent body, notably a judicial one."

10. Concerned to ensure the medical follow-up of donors, the Assembly proposes that the following article be inserted in the draft protocol: - "Systematic medical follow-up should be offered to all donors after organ removal."

11. In Article 13, paragraph 2 of the draft protocol, after the word "provided", add the word "all".

12. In Article 18 of the draft protocol, replace "Parties shall respond to shortages of organs and tissues by taking all appropriate measures to promote the procurement of organs and tissues" with: - "Parties should take all appropriate measures to promote the donation of organs and tissues".

13. The Assembly regrets that the draft protocol has not taken into account unforeseeable serious damage suffered by the donor during removal, not resulting from a medical fault. The protocol currently provides for fair compensation for either donor or recipient only where the person has suffered undue damage resulting from transplantation procedures.

14. In this connection, the Assembly recalls the spirit of the principle established in the Convention on Human Rights and Biomedicine (Article 24), which states that "any person who has suffered undue damage resulting from transplantation procedures is entitled to fair compensation according to the conditions and procedures prescribed by law". For the sake of consistency with national law or case-law in a number of countries which provides that persons volunteering to take part in research must receive adequate compensation for prejudice and damage resulting from the research, including damage not resulting from a fault, the Assembly considers that it would be desirable to include in the draft protocol an additional paragraph under Article 22, worded as follows: - "Donors must receive adequate compensation for (serious and unforeseeable) prejudice and/ or damage resulting from the organ removal, even when they are not the result of a fault."

15. In Article 22, paragraph 1 of the draft protocol (English text), replace the word "either" by the word "both", and replace the word "or" by the word "and".

16. On the question of adoption, the Assembly proposes the addition of a third paragraph to Article 20 of Chapter VI of the draft protocol, worded as follows: "The parties shall adopt appropriate legal rules and monitoring procedures to ensure that adoption, including international adoption, is not used as a channel for the transplantation of organs and tissues."

17. In Article 33, point b of the draft protocol, replace the words "or accession" by the words ", accession or denunciation".