

Presidency of the Council of Ministers



**OPINION OF THE NATIONAL BIOETHICS COMMITTEE
ON THE PROPOSAL FOR A MORATORIUM ON HUMAN
XENOTRANSPLANATION TRIALS**

19 November 1999

The Parliamentary Assembly of the Council of Europe recently examined the question of transplanting genetically modified animal organs into humans, and issued a Recommendation (No.1399, 29 January 1999) inviting member states to impose a moratorium on xenotransplantation until scientific research is able to document the human health hazards it raises.

The Council of Europe subsequently submitted this Recommendation to the Bioethics Committees of individual member states for their appraisal, in order to decide, inter alia, whether an additional protocol to the 'European Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine' (the Oviedo Convention, 1997) might be appropriate.

The Italian National Bioethics Committee (NBC) has responded to this request, and realizing the relevance of the issue of xenotransplantation to human health, it deemed it advisable to issue a short opinion on the subject, while deferring an examination of the other aspects for later discussion in a more comprehensive document.

OPINION

The NBC, consistently with the thinking expressed in previous documents (Organ donation for transplantation purposes, 7 October 1991; Organ transplants in childhood, 21 January 1994; Animal experimentation and the health of living beings, 17 April 1997; The bioethical problem of kidney transplant from non consanguineous living donor, 17 October 1997), feels duty bound to raise a number of vitally important issues for appraisal. It hopes that further advances in scientific research will make it possible to reduce the risks that indicated and the concerns to which they give rise. There are still a number of questions to be resolved and practical questions to be addressed regarding the acceptance or otherwise of a transplanted organ and the production of transgenetic animals for the purposes of organ transplantation. As things stand at present, no safe scientific conclusions have been reached, particularly with regard to the rejection of such organs and to the transmissible pathologies, giving rise to doubts and concerns that cannot be considered to be entirely without foundation. In particular, it is not yet possible to accurately identify the risks relating to the transmissibility of transgenetic infections, and particularly in terms of the effects of the relationship between genetic recombination and viral recombination.

This being so, all the issues relating to conflicts between individual interests and the protection of public health in general become all the more important.

The direct benefits to individual transplanted patients cannot be considered separately from the, admittedly less likely, risks of spreading infectious diseases among humans.

The fundamental ethical principle to be followed is to ensure a fair balance between the direct and clearly identifiable benefit to the individual patient and the serious indirect, albeit less probable, effects that might affect other, as-yet unidentifiable, individuals. Controlling the risk of spreading pathogenic or lethal biological agents would also require patients to remain under constant observation and monitoring, drastically hampering their social relations and seriously interfering with their personal freedom.

With regard to experiments on animals, consistently with the prevalent thinking in western legislation, the Italian NBC has already advised giving due consideration to the specific ethological requirements of every species, and reducing the wastage of animal lives and alleviating animal suffering. One of the aspects to be taken into account when making an ethical appraisal must be the condition and status of organ pool animals bred exclusively for the purpose of supplying organs for transplantation, whose existence could be

rendered precarious as a result of manipulating them to guarantee their histocompatibility with humans.

CONCLUSIONS

Caution is called for, precisely because of the uncertain state of knowledge, applying the ethical principle of caution and precaution. Endorsing the reasoning underlying the Recommendation the NBC therefore supports the demand for a moratorium on the experimental phase of xenotransplantation on man proposed by the Parliamentary Assembly of the Council of Europe.

The NBC also hopes that incentives will be provided for scientific research, because of the need to clarify every aspect relating to clinical practice of xenotransplants and the positive fall-out in terms of medical knowledge and the more general industrial use to which this kind of research can be put.

The NBC also emphasizes the need to encourage every opportunity to hold a public debate to disseminate knowledge of these issues and promote an ethical awareness on the part of everyone concerned, in order to be able to appraise the true level of social consensus on the issue.