

The Advisory Group on the Ethics of Xenotransplantation.

Contributors

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To all interested organisations or individuals

25 January 1996

Dear Consultee

THE ADVISORY GROUP ON THE ETHICS OF XENOTRANSPLANTATION

The Secretary of State for Health has set up an Advisory Group to look at the ethical issues surrounding transplantation of animals organs to humans. The membership of the Group is set out at Annex A.

The terms of reference of the group are: In the light of recent and potential developments in xenotransplantation, to review the acceptability of and ethical framework within which xenotransplantation may be undertaken and to make recommendations. The Group will report to the Secretary of State by summer 1996.

Xenotransplantation is the transplantation of an organ from one species to another. The Advisory Group is looking at the ethical implications of the scientific developments which contemplate the transplantation of organs from animals to humans, in place of human organs. Their interest includes the work being done to supply organs from genetically modified pigs and that involving the use of primates and will take into account potential future developments.

The Group has identified a number of issues for consideration:

- (i) whether there is a need for xenotransplantation ie whether the current and future needs for organ transplants can be met by other means.
- (ii) whether it is ethical to use, to modify genetically and to breed animals so that their organs may be used for transplant to humans. Whether the issues are different than those involved in the breeding of animals for food. Whether different issues apply for different animals.
- (iii) Should xenotransplantation be thought ethically justifiable, the considerations that should be taken into account in breeding and caring for the genetically modified animals.
- (iv) whether there is a risk of transferring zoonotic infections in the transplantation of organs from one species to another. If there is thought to be such a risk, what assessment can be made of its likely impact on the recipient of the organ and the wider population and how could such an impact be minimised.

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- (v) whether there is a need for licensing of the breeding of the animals and for regulation of the use of xenotransplants, for example, in their allocation to human patients and the need for consent of those patients.
- (vi) whether such transplants would be acceptable to the public at large.

The Advisory group would be grateful to hear you comments as an interested party in order to assist in its consideration of these issues.

Written comments should be submitted **by 29 March 1996** at the latest. If you propose very substantial comments, the Group would be grateful for an early indication of the main points of your submission. These should be set to Mr Carl Evans, Advisory Group on the Ethics of Xenotransplantation, Department of Health, Room 508 Eileen House, 80-94 Newington Causeway, LONDON SE1 6EF (FAX 0171-972-2907).

Written comments to the Group will not be made public although it is, of course, open to each contributor to make their own comments available. It is likely that a list of those who participated in this consultation exercise will be included in the final report, which may be published. If you prefer your name not to be included in such a list, please indicate this in your response.

Yours faithfully

Rachel Arrundale
Secretary to the Advisory Group

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THE ADVISORY GROUP ON THE ETHICS OF XENOTRANSPLANTATION
MEMBERSHIP

Chairman

Professor Ian Kennedy	Professor of Medical Law and Ethics, Head and Dean of the Law School, Kings College, London.
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Members

Professor Kay Davies	Professor of Genetics, Keble College, Oxford
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Nicola Davies	Barrister
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Professor Robin Downie	Professor of Moral Philosophy, Glasgow University
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Mrs Judy MacArthur Clark	Consultant in Laboratory Animal Science and Ethics
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Polly Toynbee	Journalist
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Professor Herbert Sewell	Professor of Immunology, Queens Medical Centre, University Hospital, Nottingham.
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Professor John Salaman	(retired) Professor of Transplant Surgery at the University of Wales College of Medicine.
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Dr Anthony Suckling	Director of Scientific Affairs, RSPCA
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THE ADVISORY GROUP ON THE ETHICS OF REPRODUCTIVE TECHNOLOGY

MEMBERSHIP

Chairman

Professor Ian Kennedy
Law School, Kings College London

Professor Ian Kennedy

Members

Professor Sir David
Hartley

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XENOTRANSPLANTATION: A BACKGROUND NOTE

What is xenotransplantation?

Xenotransplantation is the transplanting of organs, bone, cells and tissue from animals to humans.

Why is xenotransplantation being considered?

Over the last 40 years, human organ transplantation has developed from the transplant of a single kidney between two identical twins into a widely accepted and increasingly successful surgical procedure for transplants between unrelated individuals. Human transplantation now comprises services for renal, liver, heart and lung transplantation. Pancreatic and small bowel transplantation are in the development stage. However, as the number of people for whom a transplant might be successful has increased, other developments such as road safety campaigns, have decreased the numbers of organs available. Xenotransplantation is seen as one means of countering the organ shortfall.

What are the recent developments?

Animal products have been used routinely for some time in the treatment of certain diseases (eg pig heart valves in the treatment of patients with heart disease; pig insulin). There have also been some attempts over the years to transplant animal organs into humans, but these have not been successful, largely because the animal organs have been rejected and destroyed by the human patient's immune system.

Now, animals (usually pigs) are being genetically modified and bred to provide organs suitable for transplantation in humans. Modification of the animal embryo with human genes is designed to produce organs with human "markers" which will protect the organ from attack by the human immune system. Primates are also being used, most recently in the experimental transplant of baboon bone marrow into a person with AIDS in an attempt to reconstitute his immune system. These advances hold out, for the first time, the prospect of large-scale breeding of animals specifically for this purpose and of a regular - and more plentiful - supply of organs.

Research is progressing quickly and the first clinical trials to transplant genetically modified organs into a human could take place in 1996.

Why is there an Advisory Group on the Ethics of Xenotransplantation?

These scientific advances raise a number of ethical issues, including the appropriateness of breeding and genetically modifying animals for this purpose, the welfare of those animals, and the possibility that viruses might be transferred from the animal into the individual human patient and thence to the wider population and the consent of patients to such treatment.

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Why is xenotransplantation being considered?

Over the last 40 years, human organ transplantation has developed from the transplant of a single kidney between two identical twins into a widely accepted and increasingly successful surgical procedure for transplanting between unrelated individuals. Human transplantation now comprises services for renal, liver, heart and lung transplantation. Paediatric and small bowel transplantation are in the development stage. The number of people for whom a transplant might be successful has increased, while developments such as total artificial circulation have decreased the number of organs available. Xenotransplantation is seen as one means of satisfying the organ shortfall.

What are the recent developments?

Animal products have been used routinely for some time in the treatment of certain diseases (eg pig heart valves in the treatment of patients with heart disease, pig insulin). There have also been some attempts over the years to transplant animal organs into humans, but these have not been successful, largely because the animal organs have been rejected and destroyed by the human patient's immune system.

Now, animals (usually pigs) are being genetically modified and bred to produce organs suitable for transplantation in humans. Modification of the animal genome will ensure genes are designed to produce organs with human 'markers' which will prevent rejection from attack by the human immune system. Translating the idea of genetic engineering to the experimental transplant of human bone marrow into a person with AIDS is the nearest to reconstructing the human system. These advances hold out the first hope for progress of large-scale breeding of animals specifically for the purpose and of a regular and more plentiful supply of organs.

Research is progressing quickly and the first clinical trials to transplant genetically modified organs into a human could take place in 1990.

Why is there an Advisory Group on the Ethics of Xenotransplantation?

There is little agreement upon a number of ethical issues, including the appropriateness of breeding and genetically modifying animals for the purpose of the welfare of those animals and the possibility that viruses might be transmitted from the animal into the recipient human patient and hence to the wider population and to other animals in contact with them.