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Xenotransplantation

Summary

SUMMARY

The transplantation of animal organs into humans – xenotransplantation – has been under discussion for several years as a future supplement or even alternative to human organ donation. Besides the understandable (although not uncontested) hopes, there have been plausible warnings of real and possibly difficult-to-control risks of infection to patients, their environment and ultimately the entire population. This contradictory and tense situation and the still largely unresolved potential of xenotransplantation require a sober review of the position and unbiased assessment at all levels of society.

The present report on a commission by the Committee for Education, Research and Technology Assessment provides an overview of the international discussion and, above all, of the (research and health) policy debate on the prospects for and challenges of xenotransplantation, essays a review of the current state of scientific and medical research, outlines the legal situation in Germany and central ethical issues and uses this as a basis to draw up suggestions for further scientific, political and social debate and need for action. The report deals with xenotransplantation of discrete organs, but not of tissues or cells.

THE INTERNATIONAL DEBATE

The growing interest in the potential and problems of this new medical technology is reflected in a growing number of expert reports, opinions and other documents on xenotransplantation commissioned by governments, national agencies or international organisations. Section II summarises the results of a comparative analysis of selected publications. Overall, the analysis shows growing scepticism regarding the hope that xenotransplantation can be developed in the foreseeable future into a low-risk therapeutic approach. Another striking feature is the almost unanimous call for guidelines for binding regulations to govern the launch of clinical trials and limit their potential risks.

MEDICAL AND SCIENTIFIC ASPECTS

The state of RD on xenotransplantation (section III) can be described in terms of three key issues: overcoming rejection, ensuring physiological functionality and mastering the risks of infection. Even in human organ transplants, rejection of foreign organs by the recipient immune system is still the biggest problem,



and implanting an animal organ into a human additionally involves defensive reactions which are not only more severe but also entirely different in nature (section III.1). Of these, only the so-called hyperacute rejection seems to be controllable to some extent, primarily through advances in producing genetically modified pigs (pig organs). There is still immense need for research on the three other phases of rejection (acute vascular/delayed, cellular and chronic). The same is true of the question of physiological tolerance and functionality of the organs (section III.2), which has hardly been studied at all or has been impossible to study. Meanwhile, however, the most important issue in the debate is the substantial risk of infection (section III.3) by so far unknown probably viral pathogens, which would not only affect the recipient but also be a potential threat reaching far beyond their immediate surroundings. Here again, research is still in its infancy. Nevertheless, it is likely that clinical trials will start in only a few years. The time horizon for further dissemination of xenotransplantation is likely to be at least 15–20 years (section III.4).

A comparison with alternative technologies (artificial or bioartificial organs, therapy for the relevant diseases) also shows that these also are long-term options whose advantages and disadvantages should be thoroughly examined.

The review of the international state of research (section III.5) shows that Germany is one of the leading locations for research in the field of xenotransplantation, alongside the dominant USA and UK.

LAW AND ETHICS

The unresolved risks of infection in particular have led to the almost unanimous view – even internationally speaking – that xenotransplantation needs special regulation, at least nationally, but basically internationally. Several countries have launched initiatives in this area or have already even created institutions. An overview of the legal situation in Germany (section IV) shows that while e.g. the legislation on drugs, genetic engineering and animal protection is relevant to xenotransplantation in the area covered (although not the Transplantation Act), there is reason to doubt that existing standards adequately deal with the significance of this medical neotechnology with consequences which are potential global in their dimensions. The identifiable need for research and action here leads to the call for careful legal debate and review of legal policy by the relevant bodies.

The ethical debate (section V) shows two main emphases: consideration of moral rights and interests of humans and exploration of the possible conflict between human and animal rights and interests. The human ethical aspects of xenotransplantation (section V.1) are particularly diverse, and mostly very closely interrelated. Issues intensively discussed include e.g. reducing the shortage of transplantable organs, improving the equity in distribution, the ethics of human experiments, the current lack of any sign of an ability to deal with the infection risk, informed agreement and medical and social alternatives. The ethics of species and nature, and particularly the ethics of animals show clearly that the rights and interests of animals as »moral beings« are considerably endangered (section V.2). An ethical justification of xenotransplantation can accordingly only be achieved through carefully based and viable arguments. Ultimately, these are needed to answer the question whether human suffering has sufficient priority to justify acceptance of the sufferings and death of animals. Summarising the ethical debate, we can say that the ethical debate over whether xenotransplantation is justified is currently dominated by scepticism.

NEED FOR DISCUSSION AND ACTION

The issue of xenotransplantation can be seen as needing extensive debate and action not least by virtue of the contradictions and problems that it raises (section VI):

- > The academic community is called upon urgently to review and evaluate the state of R&D in a way which integrates overall the technological and professional aspects.
- > Politics is called upon to follow the example of other states and the recommendation of virtually all relevant expert opinions to draft and implement an appropriate regulatory strategy for xenotransplantation.
- > Society as a whole is called upon to consider ethically the possible benefits of and damage arising from xenotransplantation and to develop socially tolerable (or at least acceptable) solutions for the problems facing us.

Corresponding activities would be particularly desirable as a way of linking the debate in Germany with the significantly more advanced state of discussion elsewhere.

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