

11 March 2004

Project Officer – Xenotransplantation
Health Ethics Section
NHMRC (MDP 100)
GPO Box 9848
CANBERRA ACT 2601

Submission on the Response Paper and Draft Guidelines for Clinical Xenotransplantation Research

As stated in our submission to the first *Draft Guidelines and Discussion Paper on Clinical Xenotransplantation Research*, the Australian Association for Humane Research Inc. is totally opposed to the public health risks posed by xenotransplantation. We remain unconvinced by glib reassurances that “the NHMRC guidelines will provide a regulatory mechanism to prevent research that has not clearly shown minimal risks, and to manage the risks of research that is permitted” (paragraph 9.5).

In fact, the *Response Paper* contained several examples of similarly facile reassurances. For instance, concerns raised in paragraphs 8.17 – 8.21 regarding “whether animal organs can sustain human life” and “the potential problems for each organ” are summarily dismissed with the remarkably optimistic statement that “researchers hope that pig hearts and kidneys may function appropriately despite the significant size and other incompatibilities between the two species” (paragraph 8.22).

The same paragraph (8.22) indicates that these issues can not even be fully addressed until “the immunological barriers are overcome” (paragraph 8.22). This emphasises that xenotransplantation research would be providing false hopes to those people currently on transplant waiting lists. The vital taxpayer funds that would be wasted on such research need to be directed into existing and novel alternative research techniques, increasing human donations, and health initiatives.

Alternative research techniques

Paragraph 6.51 states “Xenotransplantation is only one of a number of approaches that might be used...” Paragraphs 8.2 and 8.4 give two examples of animal external therapies (AETs), namely the use of a pig liver cell perfusion device and the growth of human skin layers “using a culture of animal cells as a feeder layer.” It should be a priority to use human liver tissue and a human-based growth medium for such therapies, which would at least reduce the immune response due to species differences. Unfortunately, we have had correspondence with researchers who are so used to using animal-based feeder layers that they do not even recognise the material as being animal-based. They felt that as they were not using whole animals, they were not performing animal-based research. This is an indication of the lack of thought given to the ‘routine’ use of animals in research laboratories.

Increasing human donations

At the Sydney Public Meeting in February, a member of the XWP said that the “opt-out” system in place in some countries overseas would not work in Australia as this is a multi-cultural society. It is astounding that xenotransplantation research is being considered without first trialling all possible policies to increase human donation rates.

Health initiatives

Paragraph 6.49, regarding “extensive preventive health programs ... reducing health care spending on preventable diseases”, gives the impression that the existing commitment to these programs is already sufficient. We believe that this is not the case, and that additional resources and attention should be directed to lifestyle education. Such a focus could have a significant impact on the entire health system, not just in the area of organ transplants.

Public knowledge and consent

The Terms of Reference of the XWP include to:

1. undertake a community education program on xenotransplantation;
2. undertake wide consultation to obtain community views on the acceptability of proceeding with clinical xenotransplantation (paragraph 1.23).

We believe that the general public still has a very limited understanding of the word ‘xenotransplantation’, let alone the associated issues and concerns. As the public health risks intrinsic in xenotransplantations could potentially affect the entire community, it is not acceptable for xenotransplantation research to go ahead without proper community consultation and education.

Moratorium

In view of the above arguments, we call for a moratorium on xenotransplantation research in Australia.

Doubts about the public consultation process

Attendees at the Sydney Public Meeting were assured that “this is not a done deal” – that is, the Working Party will consider all submissions received before making the decision as to whether to recommend xenotransplantation should proceed in Australia, and that it is not a ‘given’ that the XWP will give this research the green light. However, even the subtitle of the Response Document “How should Australia proceed” is slanted towards the acceptance of xenotransplantation research, and that the only thing to be determined now is how it should be regulated, not whether it should be allowed at all.

We were further astonished to read a report in the Daily Telegraph of Friday 5 March 2004 opening with the line “Animal-to-human organ transplantation research should be allowed in Australia, a National Health and Medical Research Council working party will recommend.” That an announcement such as this should be made publicly before even the deadline for public submissions is incredible. Either the public consultations are a sham, or the newspaper has misrepresented the information. If the latter, I hope there will be formal action by the XWP in challenging the paper’s story.

E. M. Ahlston
President
Australian Association for Humane Research Inc.
PO Box 779
Darlinghurst NSW 1300