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AUSTRALIA

### **Animal to human transplantation research: how should Australia proceed?**

In the first round of public consultation, in response to the Draft Guidelines and Discussion Paper on Xenotransplantation, Compassion in World Farming submitted the view that Xenotransplantation should not proceed, on the basis of serious concerns regarding:

- Animal ethics
- Animal welfare
- Risk to human population
- Diversion of funds from alternatives

Our opinion was substantiated by the information provided in the publication *Animal Organs in Humans – uncalculated risks and unanswered questions*<sup>1</sup>, and remains unchanged.

We understand that our view was the more common one, i.e. that a majority of respondents, certainly in written submissions, were explicit in their opinion that Australia should **not** proceed to clinical xenotransplantation trials. Table 21 of the response document indicates that 66 submissions did not agree that animal to human transplantation trials should proceed, whereas 25 apparently thought they should. I understand that at public hearings held around Australia opposition to animal-to-human trials also was overwhelming.

It is thus with surprise and concern that we read on p.146 of the Response to the 2002 public consultation on 'Draft Guidelines and Discussion Paper on Xenotransplantation' that the Xenotransplantation Working Party (XWP) concluded:

The view of a majority of people is that, while there are some specific concerns about aspects of the procedures themselves, there are no significant *in-principle* ethical objections to the use of live organs and tissues from animals for human therapies, that would preclude any further research to develop such therapies.

The XWP then acknowledges that “some people do not share this view”. But surely this was the *majority* view of respondents in the first round?

We are also extremely concerned to see that the XWP (12.6 p.145):

As a result of ... further investigations, the working party now proposes that animal-to-human transplantation research should be permitted in Australia under a strict regulatory system .....

Surely this decision is wrong, on the basis of comment received to date and premature, given that the second round of consultation has not yet concluded.

### **GUIDELINES**

As the decision is at the very least premature, the presence and discussion of guidelines also seems premature, although we realize that should animal-to-human trials ultimately proceed, then guidelines would need to be well considered beforehand.

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<sup>1</sup> Dr Gill Langley and Joyce D'Silva, *animal organs in humans – uncalculated risks and unanswered questions*, A Report produced jointly by the BUAV and CIWF, London: 1998.

As we firmly believe that pre-clinical and clinical trials should not occur, our comment on the Guidelines themselves would seem to be out of order. However, it should be noted that Guideline 1 (Animal welfare) would be the very minimum that should be expected, given the gravity of procedures that animals undergo. Indeed para (a) should surely apply to **all** animal experimentation and is not an exceptional prerequisite of either type of trial. This comment also applies to 'Advice regarding the application of the proposed guidelines' **B. Animal Welfare**. The requirements here are no more than one would expect for any level of animal experimentation. Due regard for the needs of all animal species in a laboratory or experimental situation must be given and the needs provided for.

Pre-clinical trials are already well underway in Australia (p.155), to an inestimable degree. CIWF believes that they should not occur, due to the animal suffering involved as well as the uncertainty that xenotransplantation ever will take place on a useful scale, i.e. unnecessary waste of resources and animal life. **We therefore consider that a moratorium on pre-clinical trials should be instituted.**

### **REASONING**

No doubt the XWP has received every possible argument for and against xenotransplantation, and at this stage it is not warranted to repeat all that specifically would be relevant to our consideration. However, it is appropriate to briefly remind the WXP of some of the arguments that have led to the majority of respondents' opposition to xenotransplantation procedures.

#### *Animal ethics*

CIWF (and others) challenges the traditional arguments of a) human supremacy based on the popular religious principle, i.e. humans have souls, non-humans do not, and b) humans have a higher status, i.e. they matter more than non-humans due to the evolution of their intellectual and communicative abilities.

We thus do not consider it ethical to genetically manipulate (or to clone) non-humans for the apparent 'greater good' of the human population, particularly when this manipulation will involve the animals concerned in degrees of suffering (often extreme) and/or premature death at some stage during the extensive procedures involved to arrive at the end-goal of xenotransplantation.

Caring for the 'welfare' of a source, recipient or otherwise participating animal in any experimental procedure is a basic prerequisite and this, together with the clichéd reference to "respecting the dignity ... of animals used in a [clinical] trial" is small compensation for risking and ultimately taking the life of a sentient creature that has no say in what he or she is subjected to, or their ultimate fate.

The Principles of the (draft) guidelines (p.146, 157) speak of respecting the dignity of participants, in this case meaning the human participant, who "must give adequately informed and voluntary consent". To speak of respecting the dignity of participant non-humans, who have no possibility of being informed or giving consent and yet who will be killed, is a hollow statement.

Notwithstanding the range of ethical debate, CIWF cannot accept that it is ethical to breed animals specifically for the use of their vital organs as 'spare parts' for the human population. Apart from the likely social and environmental deprivation of source animals, it will undoubtedly result in an overwhelming number of stillborn, malformed, sick and unsuitable (i.e. not able to be used) animals.

We see that the XWP agreed with first round suggestions that animal welfare was not given enough consideration in the Discussion Paper and welcome this recognition. However, we suggest that in response to concerns noted (12.10 p.146) both the **use** and welfare of animals in studies involving them needs careful consideration.

#### *Animal Welfare*

CIWF does not propose to repeat concerns on aspects of animal welfare, as these already have been comprehensively presented to and dealt with by the WXP, if not allayed.

Nevertheless, there are some aspects of the welfare argument that we believe should be re-emphasized

- a) the untold numbers of animals that have been, are and will be involved in extensive pre-clinical, i.e. animal-to-animal trials, some of whom will suffer severe physical pain and mental torment (including the necessary administration of immuno-suppression drugs to recipient animals);
- b) the breeding and necessarily sterile living conditions of source and recipient animals, who often will suffer mental anguish;
- c) (as above) the countless stillborn, malformed, sick and unsuitable animals that will result from organ production and transplant trials.

'Behind the scenes' for the animals is not given sufficient exposure in discussion. Granted, the response to the 2002 public consultation on the draft guidelines and discussion paper acknowledges the broader public concerns regarding 'animal welfare'. But there is only so much that can be done to alleviate welfare problems in a practical sense. Pre-clinical (and clinical trials, if they eventuate) will continue to cause a), b) and c).

As RSPCA Australia pointed out in the first round of consultation:

Xenotransplantation research must pass through many developmental stages before reaching a proposal for clinical trials. These stages will involve many animals, may take place over a number of separate institutions and may be examined by a number of separate institutional AECs. At present there is no means of monitoring the development of xenotransplantation through animal-to-animal studies, since there is no requirement for these studies to be reported outside the AEC. (p.45)

And as Animals Australia has pointed out, confidentiality means that one AEC will not know what protocols of a similar type are coming before others, with the risk of duplication, use of outdated techniques and the use of more animals than should be deemed necessary.

The only way to prevent this extensive and varied suffering is to halt pre-clinicals.

#### *Risk to human (and wider animal) population(s)*

This concern, of a far different kind, seemingly has no solution as the risks are unknown in both specificity and scale. The public health risk that xenotransplantation might create a new infectious disease epidemic is a major ethical concern, acknowledged even by proponents of the procedures and their opponents in the same or medically allied profession(s). More recent health crises such as SARS and the 'avian flu' outbreak, which have crossed species as well as geographical barriers, are evidence of the reality of this phenomenon. While these crises, we understand, are now contained this is not without massive loss of life among animal populations (millions of animals killed in abominably cruel ways) as well as human loss of life. We should not be voluntarily introducing new and unknown risks, which may develop into crises of similar severity and/or scale (or possibly worse).

#### *Diversion of funds from alternatives*

CIWF stresses that its view opposing the use of animals in both pre-clinical trials and xenotransplantation should in no way be interpreted as a lack of understanding of or sympathy for the anguish, compromised lifestyles, pain, suffering and/or shortened life expectancy of humans with chronic illnesses who may be offered hope of improved quality of life and/or improved life expectancy by the prospect of e.g. organ transplantation (allo or xeno).

However, we do firmly believe that the enormous outlay of financial and other resources that is spent on researching and trialing solutions to combat problems of chronic illness would be more beneficially spent on alternatives to those that involve the use of animals, the explicit production of source animals for organ supply and which subject others to horrific experiments as recipients. In other words:

Instead, resources could be directed into improving the supply of human organs, continuing clinical trials with artificial and bioengineered organs and researching humanely the causes, diagnosis, prevention and treatment of the major diseases which create the need for organ transplantation. (Langley and D'Silva, p.5)

Australia has one of the lowest human organ donation rates in the world (*The Age*, 22 Jan 2004), but Organ Donation week in February made people more aware of the needs and benefits and substantially lifted the number of willing donors. Apparently up to 80 percent of Australians are willing to donate their own organs, but at the critical time family members may withdraw consent. More effort should be put into reversing this trend. Alternatively, Australia should adopt an 'opt out' policy on organ donation, i.e. donation is understood unless consent is specifically withdrawn before a person dies.

In an interview on 23 February 2004, on ABC Radio, the Chair of the XWP, Dr Jack Sparrow, said:

Work on stem cell research, for example, work on gene therapy, may well replace, and take over the need, so that we may not get to the stage of having to actually consider and undertake whole organ transplants from animals to humans.

If this is the prognosis of xenotransplantation volunteered by the Chair of the Working Group, why continue to subject so many animals to such pain, suffering and social and environmental deprivation unnecessarily? CIWF urges the XWP to urgently heed public comment and concerns, and certainly the view of its Chair, and recommend the cessation of pre-clinical trials,

## **CONCLUSION**

Xenotransplantation is a very complex and emotional topic of an extremely serious nature. It represents the possible saving – or prolonging, or making more comfortable and livable - of a human life but involves killing countless animals in the process, causing unknown numbers of them to suffer, often in unimaginable ways. The real extent of this aspect of the debate is little known to us or the general public

CIWF recognizes the urgent need to realize solutions to human illness that researchers believe may be found in animal-to-human transplants.

However, we believe that:

- a) the suffering for animals is too great
- b) the risks to the wider human population are also too great
- c) the benefits are uncertain
- d) the eventual realization of xenotransplantation is uncertain
- e) alternatives are available
- f) the alternatives are becoming progressively more feasible; and
- g) resources would be better put into developing alternatives than extending the suffering and death of animals involved in pre-clinical trials.

CIWF is not alone in its views and trusts that the XWP will heed the opinion of the majority of respondents to the xenotransplantation public consultation periods and reconsider its proposal that animal-to-human transplantation research should be permitted in Australia.