

What Constitutes Adequate Public Consultation? Xenotransplantation Proceeds in Australia

Peta S. Cook

Received: 5 March 2010 / Accepted: 23 August 2010 / Published online: 14 December 2010
© Springer Science+Business Media B.V. 2010

Abstract The Australian moratorium on human clinical trials of xenotransplantation was lifted in December 2009. This decision follows public consultations on whether xenotransplantation should or should not proceed in Australia, which occurred in 2002 and 2004. However, the public consultation, in its design and process, did not facilitate meaningful public engagement and involvement, thus marginalising the public and devaluing their social experiences and diverse knowledges. This brief article questions what constitutes adequate public consultation, and suggests that consensus conferences or citizen juries should be explored as a mechanism for meaningful public engagement for future public consultation exercises in Australia.

Keywords Xenotransplantation · Public participation · Decision-making · Persuasive communication · Policy development · Consensus development

Xenotransplantation is often described as a possible solution for various human health problems. This

involves three potential forms of transplantation: animal cell therapies, animal external therapies (xenoperfusion), and animal organ transplants. Animal organ xenotransplants could reduce the discrepancies between organ need and supply currently faced in human-to-human transplantation. Cellular xenotransplantation promises to reverse or partially reverse the debilitating symptoms of neurodegenerative disorders such as Parkinson's and Huntington's disease while xenoperfusion, involving the perfusion of the patient's blood through an external device containing living animal materials, could provide a patient with more time while waiting for a human organ (Xenotransplantation Working Party 2003a, 2). In the hope to achieve such ends, xenotransplantation research has focused on whether porcine endogenous retroviruses (PERV) pose an infectious risk to xenotransplantation recipients, and on overcoming the immune system response in the recipient through techniques such as plasmapheresis, depleting or inhibiting complement activity, and genetically engineering the animal source (commonly accepted as pigs) (Cooper and Lanza 2000). However, xenotransplantation is not simply a scientific endeavour. It is also a social and ethical issue that poses serious questions on, for example, the appropriate use of animal bodies, the allocation of scarce health resources, animal welfare, the possibility of cross-species viral transfer (zoonosis), how risk and its potentiality should be understood and assessed, human rights, and issues of informed consent (Cook 2007). This intermingling of public and scien-

P. S. Cook (✉)
Faculty of Arts, School of Sociology and Social Work,
University of Tasmania,
Locked Bag 1340,
Launceston, TAS 7250, Australia
e-mail: Peta.Cook@utas.edu.au

tific interests in xenotransplantation suggests the need to respect and include both knowledge bases in decision-making and regulatory processes.

In Australia, the regulation of xenotransplantation lies with the National Health and Medical Research Council (NHMRC). The NHMRC is an independent statutory agency that is the peak association in Australia for the funding of health and medical research and setting the standards of ethical conduct therein. On 10 December 2009 the NHMRC (2009) announced that, due to perceived advancements in scientific and medical research, human clinical trials of xenotransplantation in Australia would be permitted once appropriate management strategies were implemented. This decision lifted the five-year moratorium applied after two rounds of public consultation in 2002 and 2004. Following this announcement, the private biotechnology company Living Cell Technologies (2009) declared that they would apply to bring their xenotransplantation clinical trials to Australia. However despite the public consultation conducted by the NHMRC, it can be argued that the diversity of public opinion was marginalised from the decision to lift the moratorium and more generally from those decisions surrounding whether xenotransplantation should or should not proceed in Australia. While the NHMRC can be applauded for conducting public consultation on xenotransplantation, it remains open to discussion whether the public were actively involved and included in the process. In cases of technoscientific change, it is vital to capture and respect public opinion on contentious scientific issues in regulatory decision-making.

In order to consult with the community and to produce guidelines for assessing xenotransplantation clinical trial proposals, the NHMRC formed the Xenotransplantation Working Party (XWP) (2002, 4). The first XWP consisted of seven committee members, who were “from the AHEC [Australian Health Ethics Committee, who advise the NHMRC on ethical issues relating to health and research involving humans], the Research Committee and the Gene and Related Therapies Research Advisory Panel (GTRAP), the Animal Welfare Committee (AWC), the NHMRC Council, and the Consumer Health Forum” (Xenotransplantation Working Party 2002, 4). These members generally had backgrounds in clinical medicine and research, including people who were directly involved in scientific xenotransplantation

research in Australia (Xenotransplantation Working Party 2002, 135, 144). It is therefore unsurprising, as will be briefly explored, that xenotransplantation was framed in the public consultation documents within a limited scientific framework and discourse.

The public consultations conducted by the XWP occurred in 2002 and 2004, the latter of which was insisted on by the NHMRC (Xenotransplantation Working Party 2003b, 3). These processes also involved the XWP producing two consultative documents for public response (2002, 2003b), a community guide (2003b), and conducting public meetings in most Australian capital cities. However, there were a number of problems with the consultation process.

The initial problem with the public consultation was the framework under which it was conducted. While the terms of reference differed between the first and second rounds of public consultation, the consistent instruction was for the XWP (2002, 4; 2003b, 5) to draft guidelines for the assessment of xenotransplantation clinical trial proposals and to consult with the public. These terms of reference are insightful, as it appears to pre-empt the outcomes by indicating a desired conclusion. To be more specific, by requiring the XWP to design guidelines to assess clinical trials proposals, there is an implicit suggestion that such guidelines will be necessary. As will be examined soon, this was reflected throughout the consultative documents, where clinical trials of xenotransplantation are presented as inevitable: “Xenotransplantation raises ethical, social and scientific issues that need to be considered by the Australian community before animal-to-human clinical trials *are allowed to proceed*” (Xenotransplantation Working Party 2002, xiv, emphasis added). While there was a concern to understand the public perceptions of and their reception towards xenotransplantation, the terms of reference effectively restrained the consultative processes and public participation. Along with the recent lifting of the moratorium, this seems to suggest that any social issues surrounding xenotransplantation are irrelevant or can be scientifically and technically managed.

This problematic approach was reflected in the announcement of the XWP, prior to any consultation with the public, that their opinion was that xenotransplantation should proceed in Australia under guidelines (2002, xxxv) and that a moratorium on human clinical trials of whole organ xenotransplants would be inappropriate (2002, xiv). As a result, the

public consultation documents restricted the terms of debate by construing xenotransplantation as generally trouble-free. Yet the XWP (2004, 14) also acknowledged that they lacked the expertise to evaluate and adequately understand the diversity of ethical and psychosocial issues that could be problematic in the advent of xenotransplantation. Furthermore, despite the significant concerns of the public towards animal welfare, zoonosis, safety, regulation and animal welfare, and their generally negative response to xenotransplantation (Xenotransplantation Working Party 2003b, 2, 8–9; 2004, vii, 13, 21), the XWP (2004, vii, 27) continued to assert in their final recommendations that XTP should proceed in Australia.

The role of public consultation is to provide a perception of scientific credibility and legitimacy by gaining informed consent from the wider community (Irwin and Wynne 1996). However, the design and implementation of public consultation procedures can serve to marginalise the public and deny their active and meaningful engagement. In the case of the public consultation on xenotransplantation in Australia, this is witnessed by limiting the terms of reference and the public debate itself. Any possibility of productive and inclusive exchange is, as a result, restricted. This approach appears to impose a scientific agenda and framework onto the public. Therefore, the public consultations on xenotransplantation in Australia were an exercise in science communication rather than public consultation. Sociologists have labelled this the deficit model, as the public are perceived to lack an appreciation and understanding of science, and it is considered that their reception and support of scientific innovation will and should increase via an educative process (Irwin and Wynne 1996). The existing divide between science and the public is thus maintained and perpetuated, with science placed in an authoritative position that closes discursive community debate. This denies that the public may be justifiably sceptical (Wynne 2006), or have their own valid concerns informed by their own social knowledges and experiences. The relationship between science and society is therefore constructed as adversarial.

While difficulties remain with public consultation and participation processes, and tense relations between the public and science continue, these should not be reasons to abandon meaningful two-way dialogue. In public consultation, we need to move away from an imposed, standardised and top-down

model of privileging scientific knowledge over all other forms of knowledge and towards consultation that genuinely includes and engages the public, and values their input on an equal status with the scientific point of view. These different positions and viewpoints need to be respected.

Alternate models that can facilitate inclusive public engagement and encourage deliberation are consensus conferences and citizen juries. These democratic models generally involve a small panel of between 10 and 20 citizens who, after receiving general information on the topic and having listened to presentations from a variety of experts and stakeholders, collectively debate and discuss those issues and topics they feel are of major concern or importance. This typically occurs over several days (Leroux et al. 1998; Einsiedel and Ross 2002). The ultimate aim is to reach an informed decision that will ideally be a group consensus. For consensus conferences they may conclude with a conference to inform the wider public of the findings, while citizen juries generally result in a report that is submitted to the commissioning body (Leroux et al. 1998; Einsiedel and Ross 2002). Citizen juries were successfully employed to engage the public with xenotransplantation in Canada (Einsiedel and Ross 2002). The Canadian consultations also included documents that provided basic information on xenotransplantation on which the public could deliberate, rather than documents advancing a partisan perspective. For all forms of public consultation, however, public participation must not be constrained by pre-imposed expert knowledges and frameworks; it should be timely and well-organised and embrace a deliberative approach rather than constant deconstruction of opposing points of view (Jasanoff 2003).

This paper does not argue that scientific knowledge should not play a role in the Australian xenotransplantation debate. Science does have a significant and important role to play, but this should not translate into a guaranteed authority that determines the concerns, terms and limits of debate. To repeat, xenotransplantation is a contentious development that raises serious ethical and social concerns. This means that it is integral to meaningfully include the public in a direct, inclusive and respectful manner in regulatory decision-making. Through the XWP, the NHMRC made a start on this journey in 2002 and 2004. The next step is to move from an educative and consultative approach to an active

participation and engagement of the public that involves a two-way dialogue and debate, as well as providing non-partisan documents. Furthermore, regulatory decisions should be made with the public and their position in mind and not solely based on, though equally informed by, scientific and technological assessments. Only through this type of approach can the public be truly respected and involved.

References

- Cook, P.S. 2007. Informed consent and human rights: Some regulatory challenges of xenotransplantation. *Social Alternatives*. 26(4): 29–34.
- Cooper, D.K.C., and R.P. Lanza. 2000. *Xeno: The promise of transplanting animal organs into humans*. New York: Oxford University Press.
- Einsiedel, E.F., and H. Ross. 2002. Animal spare parts? A Canadian public consultation on xenotransplantation. *Science and Engineering Ethics* 8(4): 579–591.
- Irwin, A., and B. Wynne. 1996. Introduction. In *Misunderstanding science? The public reconstruction of science and technology*, ed. A. Irwin and B. Wynne, 1–17. Cambridge: Cambridge University Press.
- Jasanoff, S. 2003. Technologies of humility: Citizen participation in governing science. *Minerva* 41(3): 223–244.
- Leroux, T., M. Hirtle, and L. Fortin. 1998. An overview of public consultation mechanisms developed to address the ethical and social issues raised by biotechnology. *Journal of Consumer Policy*. 21(4): 445–481.
- Living Cell Technologies. 2009. *Living cell technologies considers Australian trials following lifting of animal cell transplant ban*. http://www.lctglobal.com/downloads/cms_latest_news/2009-12-09-31mnq6y96z9q8p.pdf (accessed December 10, 2009).
- National Health and Medical Research Council. 2009. *Clinical trials involving animal-to-human transplantation*. http://www.nhmrc.gov.au/_files_nhmrc/file/media/media/rel09/091210-xenotransplantation.pdf (accessed December 10, 2009).
- Wynne, B. 2006. Public engagement as a means of restoring public trust in science—hitting the notes, but missing the music? *Community Genetics* 9(3): 211–220.
- Xenotransplantation Working Party. 2002. *Draft guidelines and discussion paper on xenotransplantation*. Canberra: Commonwealth of Australia. http://www.nhmrc.gov.au/_files_nhmrc/file/about/committees/expert/gtrap/xeno.pdf (accessed December 10, 2009).
- Xenotransplantation Working Party. 2003a. *Animal-to-human transplantation research: A guide for the community*. Canberra: Commonwealth of Australia. http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e54.pdf (accessed December 10, 2009).
- Xenotransplantation Working Party. 2003b. *Animal-to-human transplantation research: How should Australia proceed?* Canberra: Commonwealth of Australia. http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e55.pdf (accessed December 10, 2009).
- Xenotransplantation Working Party. 2004. *Animal-to-human transplantation (xenotransplantation): Final report and advice to the National Health and Medical Research Council*. Canberra: Commonwealth of Australia. http://www.nhmrc.gov.au/about/committees/expert/gtrap/_files/xenotrans.pdf (accessed July 10, 2007).