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The Cultural, Ethical and Spiritual Aspects of Animal-to-Human Transplantation

A report on xenotransplantation by
Toi te Taiao: the Bioethics Council

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Letter from the Chair

It is with much pleasure that Toi te Taiao: the Bioethics Council presents the Minister for the Environment with this report into the cultural, ethical and spiritual aspects of xenotransplantation.

Having earlier sought the views of New Zealanders on the use of human genes in other organisms, it is timely that the Council has now focused on animal-to-human transplantation. Worldwide interest in xenotransplantation's potential to cure or alleviate a number of serious health conditions - diabetes and Huntington's disease among them - is growing. However, there are also concerns about the risks of xenotransplantation, especially the potential for cross-species infection, which have not yet been reliably quantified.

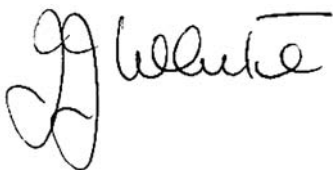
Xenotransplantation is not presently undertaken in New Zealand. Under the current legislation, xenotransplantation trials require the specific approval of the Minister of Health and must meet strict criteria. To date, no applications to conduct trials under this legislation have been made. However, the relevant section of the Medicines Act 1981 is due to expire at the end of 2006.

A decision about whether New Zealand allows xenotransplantation turns on more than a technical assessment of safety alone. Safety is itself an ethical issue: the way people think about it is inextricably tied up with their cultural, ethical and spiritual outlook. Decisions about xenotransplantation must include cultural, ethical and spiritual considerations.

The recommendations we present here have been informed by the views of New Zealanders. As we did in 2004, when looking at the use of human genes in other organisms, we have engaged in a nationwide public dialogue process. Once again, we have encountered a high level of interest and passion among people of all shades of opinion and knowledge. Their willingness to share their experiences and views with Council members and each other, to engage with viewpoints sometimes diametrically opposed to their own, and to reflect on and deepen their own understanding, were hallmarks of the dialogue process.

It is not always easy for people to talk about their cultural, ethical and spiritual values, and to bring them to bear on a complex and developing subject such as xenotransplantation. That New Zealanders were prepared to do so thoughtfully and passionately is a privilege for us to have shared. But it is also a testament to the value of dialogue as a tool for shaping decisions - even though it is full of challenges, and may be more costly and time-consuming than the traditional consultative approach.

Toi te Taiao: the Bioethics Council has great satisfaction in presenting the Minister, and the people of New Zealand, with the outcome of our dialogue and deliberations on xenotransplantation.



Jill White

Chair

Toi te Taiao: the Bioethics Council

1. Introduction

1.1 Background

Toi te Taiao: the Bioethics Council was appointed by the Government in December 2002. Its goals are: “To enhance New Zealand’s understanding of the cultural, ethical and spiritual aspects of biotechnology and ensure that the use of biotechnology has regard for the values held by New Zealanders”. It does this by:

- providing independent advice to the Government on biotechnological issues involving significant cultural, ethical and spiritual dimensions
- promoting and participating in public dialogue on the cultural, ethical and spiritual aspects of biotechnology, and enabling public participation in the Council’s activities
- providing information on the cultural, ethical and spiritual aspects of biotechnology.

The Council’s first major public dialogue project, on the use of human genes in other organisms, took place in 2004. The Council then turned its attention to xenotransplantation: the transplantation of cells, tissues and organs from animals to humans. In early 2005, it released a public discussion document, *The Cultural, Spiritual and Ethical Aspects of Xenotransplantation: Animal-to-Human Transplantation*, paving the way for a series of nationwide dialogue events during April and May. The public also had the opportunity to participate in an online discussion forum, and to make written submissions.

This report presents the results of that dialogue process, and the reflections of the Bioethics Council on the issues raised in the dialogue. It does not duplicate background information on xenotransplantation already presented in the discussion document.¹

Why Xenotransplantation?

There is growing interest in xenotransplantation as a means of improving the survival and health prospects of people with life-threatening illnesses. It also offers a possible solution to the worldwide shortage of human tissue and organ donors.

Xenotransplantation is not a new idea: animal-to-human transplants have been unsuccessfully tried for over 250 years. But until relatively recently, the serious immune responses that xenografts (transplanted organs, tissues or cells) caused the recipient had seemed insurmountable. Now, new scientific developments have challenged this assumption. Genetic modification of the source animals has been heralded as a way of reducing the chances of rejection. At the same time, increasingly sophisticated anti-immune drugs have been developed.

Building on these developments, researchers have worked on several kinds of xenotransplantation procedures. Some offer entirely new forms of treatment; some build on existing treatments. Some require cells, tissues or organs that have been genetically modified; others do not.

The xenotransplantation procedures currently under investigation around the world are broadly of three kinds:

animal cell therapies: animal cells are transplanted into a human to treat or cure a specific problem. For example, insulin-producing cells from a pig’s pancreas are transplanted into a person with type 1 diabetes. The pig cells produce insulin and eliminate the need for further insulin injections.

1. This is available from the Council, or can be downloaded from www.bioethics.org.nz.

animal external therapies: these take place outside the human body. For example, pig liver cells are transferred to an external device also containing the blood of a patient with liver failure. The pig cells help remove toxic substances from the blood and stabilise the patient until a human organ is available or the liver recovers.

animal organ transplants: a whole animal organ is used to replace a failed human organ.

Some of these forms of xenotransplantation - notably external and cell therapies - are relatively advanced in their development. The development of other procedures, especially whole organ transplants, remains in its infancy.

Animal-to-human transplants are not currently carried out in New Zealand. An application to conduct an animal-to-human transplant clinical trial was made to the Ministry of Health in 2001. It was declined on clinical safety grounds. That same year, the Royal Commission on Genetic Modification recommended that the Bioethics Council develop ethical guidelines for xenotransplantation involving genetic modification.

In response to these developments, the Government passed an amendment (Part 7A) to the Medicines Act 1981. It stated that xenotransplantation trials could only be undertaken with the approval of the Minister of Health, and in accordance with strict criteria. No applications have yet been made to carry out trials under this provision.

But the situation is soon to change. Part 7A expired in mid-2005 and was extended to the end of 2006. After that, new provisions regarding the possible regulation of xenotransplantation will need to be in place.

It is against this background of renewed international interest in xenotransplantation, and pending legislative change, that the Bioethics Council has sought the views of New Zealanders on the cultural, ethical and spiritual aspects of this biotechnology, and is now making recommendations to Government.

Xenotransplantation decisions and the role of the Bioethics Council

It is not our role to say whether or not xenotransplantation is safe or effective. This will be determined by the Government on the basis of advice from the Ministry of Health, reflecting the best available scientific evidence about the safety and effectiveness of xenotransplantation.

But in asking the Bioethics Council to examine the cultural, ethical and spiritual dimensions of xenotransplantation, the Government is signalling that any decision about the safety and effectiveness is also about cultural, ethical and spiritual factors. Safety is itself an ethical issue that requires people to question some of their most deeply held values. Is it wrong to do things that may carry a certain element of risk? To what extent does the presence of risk justify a curtailment of individual freedoms? As human beings, do we have a fundamental duty to respond to the suffering of others?

Moreover, there are other considerations beyond safety and its ethical aspects. As one participant in our online discussion forum said: 'Even if science can demonstrate a good safety record, plus highly effective therapeutic outcomes, that in itself does not necessarily make xenotransplantation socially acceptable.'

In this report, we describe what we heard from New Zealanders about the cultural, ethical and spiritual dimensions of xenotransplantation. We also present our own conclusions, based on what we heard, and make a series of recommendations to Government.

Toi te Taiao: the Bioethics Council and the Treaty of Waitangi

One of the Bioethics Council's key tasks is to engage with Māori and with Māori cultural, ethical and spiritual views, consistent with the Government's commitment to the Treaty of Waitangi.

The Council's Māori Working Group has been instrumental in helping the wider Council define its Treaty role, and put it into practice in the xenotransplantation dialogue, in Council deliberations and in its wider work.

In essence, we see our key Treaty responsibilities as ensuring that Māori voices are heard in all the Council's dialogue and deliberations, and that the wider New Zealand public gains an understanding of Māori issues and te ao Māori. This means:

- ensuring our processes allow us to engage with a wide range of Māori: lay, professional and political (which may involve giving advice to ministers other than the Minister for the Environment alone)
- seeking out the plurality of Māori voices in New Zealand, without attempting to impose consensus where there may be none
- incorporating Māori voices and perspectives in all the Council's communications with the New Zealand public
- ensuring that all the Council's recommendations and decisions acknowledge the wishes and rights of Māori to continue to live as Māori in Aotearoa New Zealand.

The Bioethics Council's commitment to 'dialogue' as a way of engaging with the public is part of its developing role under the Treaty. As we describe in Section 2.1, dialogue is a very different process from other forms of government-led consultation. The Crown's Treaty-based consultation has traditionally involved the presentation of draft policies to Māori for discussion through the select committee process. Throughout the public dialogue on xenotransplantation, we noted that some individuals and groups were unfamiliar with the dialogue-based approach. It may take time for this to change, and for the Bioethics Council to refine its processes in order to engage effectively with a wide range of Māori interests. More reflections on the xenotransplantation dialogue process are contained in Appendix A.

The role of the Māori Working Group

Māori have a significant presence on the Bioethics Council, and the Māori Working Group contributes to a wide range of projects - including the dialogue on xenotransplantation.² Members of this group:

- give advice to Council on Māori issues, drawing on their own expertise (which includes education, science, health, community development and Tikanga Māori) and the expertise and knowledge of the wider Māori community
- seek to develop ways for Māori to engage in the dialogue on xenotransplantation and on biotechnology more generally
- examine the relationship between Tikanga Māori and biotechnology, including xenotransplantation.

2. Members of the Māori Working Group on xenotransplantation are Waiora Port, Piri Sciascia, Chris Cunningham, Chappie Te Kani and Charlotte Severne.

1.2 Structure of this report

This report is, firstly, an account of what we heard in the dialogue process. It then presents the results of our deliberations, including our recommendations to Government.

Section 2 describes how the dialogue process was designed and implemented. Section 3 describes what we heard on the following themes: culture, ethics, spirituality and human need; Māori dialogue and deliberation; the interests of animals; and individual rights and public risk. Throughout, we include quotations from the online discussion forum, written submissions, and the dialogue events themselves. These convey something of the flavour of the dialogue, the strength of people's beliefs, and the range of viewpoints and voices we heard from.

Section 4 summarises the Council's thinking on each of those themes. In some cases, we make specific recommendations for action. These are brought together in the summary of recommendations in Section 5. Finally in Appendix A, we include some reflections on the dialogue process itself that point to the benefits and challenges of this particular approach. A glossary of some of the specialised terms used in this report appears at the end.

2. Developing the project

2.1 The dialogue process

The Bioethics Council strongly supports the use of ‘dialogue’ as a means of building deeper understanding of one’s own views and the views of others. Dialogue is not about persuading people to adopt a particular position. Instead, it involves people - often with very different or opposing perspectives - meeting together in an environment of mutuality and trust; expressing themselves without fear of attack or judgment; and exploring, clarifying and developing their own thinking and that of others. It is a very different process from traditional forms of government consultation.

As a means of shaping future decisions about biotechnology in New Zealand, dialogue offers some important benefits. It gives the public the chance to articulate and understand a wide range of values and beliefs. The face-to-face exchanges allow constructive relationships to develop between people with opposing viewpoints. And it allows the Government to better understand what is at stake for people, and how they expect to see their values and beliefs expressed in political and economic decisions.

Some reflections on the xenotransplantation dialogue - what worked well, how it could have been improved - are presented in Appendix A.

2.2 Dialogue events

Based on our experience of running dialogue events in 2004, the Bioethics Council decided to offer a series of two-stage meetings and hui. Participants who attended the initial session would be invited to ‘reconvene’ for further discussions at a follow-up session a few weeks later.

Eight reconvening events (16 sessions in all) were scheduled across the country. All events were open, but two provided opportunities to focus on Māori perspectives in a Tikanga Māori environment, and another provided for open participation in a bicultural environment.

Participants included people or groups already on the Bioethics Council’s database and others who found out about the events from the Council’s publicity and the media. The venues and numbers attending each event are shown in Appendix A.

The sessions were conducted by trained facilitators, who had been briefed on xenotransplantation by the principal advisor of the New Zealand Medicines and Medical Devices Safety Authority. At least one member of the Bioethics Council also attended each event, gave a brief introduction to xenotransplantation, and outlined the present regulatory environment.

The Bioethics Council’s discussion document, *The Cultural, Spiritual and Ethical Aspects of Xenotransplantation: Animal-to-Human Transplantation* was circulated to participants beforehand. Although not all had read the document before the first session, it provided a starting point for discussion of the following broad themes:

- What is xenotransplantation and why is it being considered?
- How well does it work and what are the risks?
- Xenotransplantation and cultural, spiritual and ethical issues:
 - spirituality, culture and human need
 - Māori and xenotransplantation
 - the interests of animals
 - individual rights and public risk
 - decisions about xenotransplantation in New Zealand.

At the first session of each event, the nature and purpose of 'dialogue' was explained to participants. Working in small groups, they were invited to identify key cultural, ethical and spiritual issues that concerned them. Their comments were recorded on flip charts and presented to the full group, who could then record further responses or reflections. At the end of the session, participants were asked to do some 'homework' - in the form of discussing xenotransplantation issues with friends, family and others - before the reconvened session.

At this second session, participants reviewed the results of their 'homework' in new small groups, recording new ideas and responses. They continued to explore specific issues, the exact meaning of 'cultural' 'ethical' and 'spiritual', and the significance of these concepts to xenotransplantation. Participants had the opportunity to provide a written evaluation at the end of each session.

2.3 Online discussion forum

A web-based discussion forum began in February 2005. The themes for discussion were set out along broadly the same lines as in the discussion document.

Over a four month period, the online discussion forum received almost 2,200 visits. Of the 400 registrants, there were 91 contributors on 30 topics. More than 350 comments were posted.

2.4 Written submissions

People were invited to make written submissions on xenotransplantation, using forms inserted into the discussion document and also available on the Bioethics Council website. Submitters could base their submissions around 12 key questions exploring the themes outlined in the discussion document, and most chose to do so. However, submitters were free to respond in any way they wished, and some chose to focus only on particular issues. We received 289 submissions.

3. What the Bioethics Council heard

This section aims to reflect something of the richness and diversity of the public dialogue on xenotransplantation. It is not intended to provide a representative or quantitative sampling of the views expressed, nor do any of the comments necessarily represent the Council's own views. The quotations have been extracted from the online discussion forum, the written submissions, and the facilitators' notes from the dialogue events.

3.1 Culture, ethics, spirituality and human need

Introduction

Thinking about xenotransplantation requires us to confront our fundamental cultural, ethical and spiritual beliefs - about what it means to be human; about our relationships with other people, nature and other species; and about the degree to which factors such as compassion and human need should influence decisions about biotechnology.

Even if we seldom examine our cultural, ethical and spiritual beliefs, or if we consider them to be relatively unimportant, they are integral to the way we live our lives and the decisions we make. Whether we are conscious of them or not, our beliefs provide us with a framework for making sense of the world around us and for regulating our relationships with it.

This section describes the range of thinking we heard on cultural, ethical and spiritual issues - including identity and human need.

What cultural, spiritual and ethical factors are important to people?

Throughout the dialogue process, we heard viewpoints that were strongly shaped by specific religions or cultures - mostly Christian, Māori and Pakeha. We also heard many world views that sat outside a formal religious or cultural framework: an 'ecological' belief in the integrity and inter-dependence of all species, for example, or a humanistic belief in the duty of every person to help their fellow human beings. Some had spiritual and cultural beliefs they shared with a wider group to whom they felt connected by ethnicity, faith, age, political outlook or some other common feature. Others considered their beliefs to be individual and essentially private.

The following summaries and quotations provide a taste of some of the very wide-ranging spiritual, ethical and cultural viewpoints we heard. However, it must be emphasised that the labels applied here to various viewpoints are far from neat or finite. Elements of all might be found in any one individual, and many people who would not identify themselves with a particular label (for example, 'Christian' or 'ecological') might very well share those views.

Religious viewpoints

A recurrent theme among those who identified themselves as Christian was the 'love thy neighbour' principle. They said this compelled a compassionate response to the suffering of other human beings, including through xenotransplantation. (This strongly compassionate view was also expressed by others with no religious affiliations.)

'Compassion is an essential part of Christianity, and of many world religions ... [We] have a role in using our knowledge and abilities to relieve suffering and pain.'

The desire to cure or relieve suffering was held in balance, by some Christians, with an acceptance of death. To them, the desire to preserve life must be weighed against people's duty to care for the wider community and environment, and to respect other life forms. The over-riding importance of the sanctity of life in some faiths (notably Judaism) was discussed by some, who said it provided people with an acceptable faith-based rationale for xenotransplantation.

Some Christians rejected the idea that humans should receive animal transplants, stating that we are made 'in God's image'. Xenotransplantation would distort this God-given image.

Other Christians talked about spiritual beliefs that shaped their thinking on the use of animals in xenotransplantation. Views were quite diverse, reflecting differing interpretations of the creation story in Genesis. Some emphasised humans' responsibility for and to the whole of creation. This involves a duty of stewardship for the environment and for other species.

An alternative theological view was expressed by the 'dominionists', who held that human beings were divinely sanctioned to exercise authority over other forms of life. Without this authority, they said, farming would be impossible.

Māori viewpoints

There was a wide diversity of Māori viewpoints - not all of them focused on cultural and spiritual issues - and this is discussed more fully in Section 3.2.

However, a general theme was the strength of spiritual beliefs among Māori, and the sense of a Māori world view that pervaded all corners of everyday life. The importance of Tikanga Māori to regulate the relationship of Māori to the wider world was strongly emphasised, as was its development.

Some Māori were very concerned about the implications of xenotransplantation for whakapapa (genealogy), mauri (the life force), and personal tapu (sacredness). Some believed such biotechnologies threatened to irreparably disrupt relationships between human beings and the natural world.

'There will be times when we may have to forsake power for powerlessness in the face of human suffering and death for the sake of respecting our role as stewards of creation.'

'Within Judaism, xenotransplantation is acceptable because the over-riding value is to save life. This over-rides other considerations such as the prohibition on the consumption of pig flesh.'

'Humans have a relationship with the divine that differentiates them from the rest of created order. There is the concept of humans caring for other creatures as well as acting over them. This notion of humans as co-creators is sometimes employed as a way of expressing this dimension of human nature.'

'I believe that God put Man a little higher than animals.'

'Mauri is the energy life force or unique life essence that gives being and form to all things in the universe. Tikanga Māori has emerged around this duty, bringing with it an intimate knowledge and understanding about local environments and a set of rules that guides our way of life, both spiritual and secular.'

'As tangata whenua, we don't split ourselves up culturally and spiritually, it's called taha wairua. We don't need to debate the ethics because there is our implicit understanding of mauri and acknowledging the life force of every living thing.'

'Whakapapa is a taonga tuku iho. It is the line in the sand that we do not cross, a sacred thing.'

A strong sense of Māori responsibility and guardianship – kaitiakitanga – for the environment was expressed by many. This implied respect for all life forms, including the animals used in xenotransplantation.

For some, an absence of tikanga and kawa to deal with xenotransplantation was an over-riding issue. They felt it was impossible for Māori to participate as Māori in xenotransplantation without it being enabled by tikanga. Some believed tikanga never would – or should – accommodate xenotransplantation; others that it could be developed or modified, on the basis of more knowledge and understanding.

The importance of collective views and decision-making to the Māori world view was also emphasised by some participants. This meant whānau and hapū would sometimes be considered to have the same decision-making rights as an individual, with implications for decisions like organ donation and medical treatment.

Other world views

We heard from many others with world views which were not formally religious or cultural.

A ‘species integrity’ argument was advanced against xenotransplantation by some, particularly those with what might be called an ecological world view. These people often spoke of a connectedness between networks of species, or a fragile natural balance that would be disrupted by xenotransplantation. They said that the integrity of each individual species was transgressed when parts of one species were mixed with another. Some also said that each species had its own innate value, independent of its usefulness to humans. While this tended to mean opposition to xenotransplantation, someone who identified herself with the Gaia movement said that the technology was acceptable because all species are equal parts of ‘mother earth’.

‘Ma te ira tangata e tiaki te aitanga o nga Atua – it is the responsibility of mankind to protect the offspring of the Gods.’

‘We are accountable, not to God, but to sustaining fertility, ensuring whakapapa and ensuring the environment is not compromised by the individual need of another.’

‘For Māori, this is a serious misconduct of tikanga (protocol) and will have a serious impact on our values and beliefs that guide and assist us in Te Ao Marama (the world of light).’

‘Until the advent of cell-phones, tikanga could not take account of them either.’

‘Māori identity is primarily based in place and social group, as defined by maunga, awa and marae as well as iwi, hapū and whānau. This is not to say that individual Māori cannot make up their own minds on issues, but more frequently it is a group process, rather than an individual one.’

‘The individual with the problem is the one who should decide whether they should benefit. Each Māori is an individual.’

‘I have a set of values that revolve around respect for the environment and connectedness between all living things.’

‘All life exists in an equilibrium on our planet and all should be cared for.’

‘A widely held view by Māori is that transgenics ... is a breach of integrity of species and an offence to whakapapa.’

‘My cultural perspective is that there is a food chain which is part of nature, which sustains and supports us, and the better we work in harmony with it the better off we are.’

Many with non-religious viewpoints shared the ‘stewardship’ position we heard from Christian participants. The responsibility of humans for the wellbeing of animals was strongly expressed. But there was some diversity in what people saw as the implications of stewardship. We heard from some people that a degree of suffering to animals was permissible if it meant human lives would be saved. For others, animal suffering was never to be contemplated, regardless of the benefits to humans.

Some people found it hard to define what ‘cultural’ and ‘spiritual’ actually meant. We heard from some people who felt they weren’t spiritual, or that they didn’t have a culture. Others expressed frustration that they didn’t have an adequate vocabulary to describe their cultural or spiritual viewpoints. An interesting feature of the dialogue events was to see many of these participants progressively become more able to define and describe these terms, and to identify what they meant in their own lives.

Identity

In discussing issues of personal identity, some people clearly distinguished between forms of xenotransplantation involving whole organs and those involving tissues and cells.

Many people felt the use of whole organs – and especially brains and reproductive organs – presented the greatest challenges to their sense of personal identity. (These are also the organs that the Catholic Church, while generally supporting the use of xenotransplantation, defines as intrinsically linked to personal identity and therefore ethically unacceptable to use³.) With reproductive organs, there seemed to be concerns about the possibility of non-human genes entering the human gene pool – in other words, a concern for future generations. It was harder to discern the reasons for people’s obvious discomfort about the use of brains in xenotransplantation, and whether this also extended to neural cells and tissue.

There was some discussion about the link between personal identity issues and possible stigmatisation of xenograft recipients. Those who saw xenotransplantation as a technology that made people less than human questioned how they would relate to someone they knew who had a xenograft.

‘I believe we should treat animals humanely ... but I do believe that a human life is worth more.’

‘You cannot be a human with animal parts.’

‘I believe that as long as the recipient of the transplant maintains their genetic and psychological identity, there is practically no difference.’

‘The brain and reproductive organs determine a person’s identity to a greater extent than other organs and as such should be regarded as off limits.’

‘I don’t believe in any religion. But in my culture we believe in being buried or cremated with all body parts intact ... I would find it hard to accept that a part of me has been replaced by something that initially belonged to an animal.’

‘[Xenotransplantation recipients] could be judged, discriminated against or thought of as somewhat abnormal. This would have a huge effect on people’s view of themselves.’

‘A man is no different because his liver is that of a pig’s. A man’s personality defines a person.’

3. Pontifical Academy for Life, Prospects for Xenotransplantation: Scientific aspects and ethical considerations, http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20010926_xenotrapianti_en.html, pp 9-10.

From some who supported xenotransplantation or had benefited from it, we heard some very different views about the capacity of xenotransplantation to actually enhance identity. We heard that xenotransplantation had become a very strong and positive part of their identity.

Human need

Human need is a factor that can challenge our cultural and spiritual beliefs to the utmost, especially when a serious illness affects us or someone close to us.

But, as we heard, human need is not just a matter of personal self-interest. For many, the sanctity of life, and the need to preserve it by responding to human need, is a fundamental principle of humanity and/or a religious duty. For some people, this extends to a belief that we are failing in our duty to our fellow-human beings if we do not use all available medical technologies and knowledge to save lives. Human need is therefore very closely linked with spiritual and cultural values.

Many Māori – who suffer disproportionately poor outcomes from the conditions which xenotransplantation may help alleviate – spoke of the dilemma of having to weigh up the urgent needs of **whānau against their cultural and spiritual** objections to the technology.

Many people who were uneasy about xenotransplantation, pointed to alternatives. They said preventative health measures and emerging technologies such as stem cell therapy might equally well meet serious needs, and called for them to be investigated in preference to xenotransplantation. Some felt that research effort and funds were being diverted away from these promising therapies by the present focus on xenotransplantation. Others felt that xenotransplantation was effectively an ‘old technology’ and other forms offered more exciting possibilities. Some called for the ‘presumed consent’ model to be introduced in New Zealand as a way to increase the number of donated organs available for transplants.

But we also heard doubt about whether these alternatives were promising responses to the serious conditions that xenotransplantation might treat.

‘Diabetes does have a very profound (adverse) effect on identity and this is not well understood by others. We believe successful xenotransplantation would have a very positive effect on the recipient’s sense of self and his/her place in the world.’

‘As long as there is a chance of a greater good being done for individuals and communities with any potential scientific advances, then we should not shy away from our responsibility to pursue any and all possibilities ... whilst exercising good risk management.’

‘Māori philosophy is based around the concept of “natural-ness”... However, the European-derived, colonizing culture has had a major impact on Māori thinking and Māori worldviews, so that no generalisation based on old Māori worldviews is possible in the 21st century. However, confronted with our own death, or the death of someone close, would we actually live up to previously stated ideals, or would we change our position?’

‘A safer alternative is the possibility of regenerating organs and tissues from the patients’ own stem cells.’

‘Type 2 diabetes could be significantly reduced by healthy diet and frequent exercise.’

‘Allowing xenotransplantation could potentially stifle valid research into more effective and safer treatments.’

Another view we heard was that xenotransplantation was simply going too far in our quest to cure illness or disease. Some felt that many of us have become increasingly unwilling to accept the inevitability of death and expect to defeat it, by whatever means.

Discussions of this topic tended to be age-specific. Among older people, we heard a greater acceptance of the inevitability of death, which meant they would not choose xenotransplantation for themselves. However, some said that if a child or grandchild was in need, they might think quite differently.

On the other hand, some younger people and parents of young children spoke passionately of the need to prolong lives they felt would otherwise be prematurely cut short. They felt very strongly that their needs should not be denied by the spiritual and cultural values, or squeamishness, of others.

For some people, the question of human need also involved issues of equity and access. They expressed concerns about the desirability of funding expensive xenotransplantation research and trials which only a few people would benefit from, nationally and globally. The opportunity cost – the other urgent health needs that remained unmet as a result of the focus on xenotransplantation – was a cause of concern to some.

On the other hand, we also heard the view that xenotransplantation, if it worked, might well prove less costly than some treatments – such as insulin or dialysis – currently available in the public health service.

Some common themes

Taking into account the different terms people used to articulate their cultural, ethical and spiritual viewpoints – and the fact that some people found them hard to articulate at all – we heard that the following principles were especially important to New Zealanders:

- the need to respond compassionately to the suffering of people and animals
- regard for the sanctity of human life
- freedom of choice
- kaitiakitanga and stewardship for the earth and its life forms.

‘Maybe we need to do some work around our cultural attitudes to death – accept that we too are parts of a life cycle, that we too will die. We are part of nature too, and we should learn from our past mistakes to work with nature, rather than fight against it with increasingly bizarre and risky science.’

‘I’d vigorously dissuade [a family member wanting to undergo xenotransplantation] ... and encourage them to be reconciled with God, so that death or long term suffering would be less threatening.’

‘I would do everything in my power to maintain the health and well-being of my children. Anything less is tantamount to neglect.’

‘What parent would not want research [into xenotransplantation] to go ahead which could potentially lead to a cure [for Type 1 diabetes]? By stopping this research you are denying us this choice and sentencing our children to a lifetime of fending off this slow and horrible killer.’

‘Ensure that xenotransplantation is provided to people who deserve it, not those with the most money.’

‘Reducing poverty, not increasing the availability of high-tech medicine to the few, is likely to be the most effective way of increasing life expectancy in the developing world.’

‘We have many spiritual and cultural attitudes ... and yet much unity.’

Views on the implications of these principles for xenotransplantation differed widely between individuals and groups, as did the ways in which they reconciled tensions between them.

But perhaps the widest differences arose on the question of how cultural, ethical and spiritual beliefs should influence decisions on xenotransplantation. This often arose in discussing the nature of the decision-making process itself: how individuals and groups were able to influence decision-making, and the rights of minorities to have their views heard.

From some, we heard that it was crucially important for Government to take account of New Zealanders' spiritual and cultural beliefs in deciding whether to allow xenotransplantation. Among both Māori and non-Māori, this was sometimes linked to a view that xenotransplantation was primarily a Treaty issue. The cultural, ethical and spiritual beliefs of Māori, as tangata whenua, had a special place in the decision-making process and needed to be reflected in the outcome.

Others said cultural, ethical and spiritual beliefs were important, but not exclusively so. They should be considered by decision-makers equally with issues of science, effectiveness, safety and health risks.

Another viewpoint was that cultural and spiritual considerations were simply too emotive and subjective to be taken into account. Science alone should provide the evidence on which decisions about xenotransplantation are made.

Discussion of this question tended to involve a debate about individual choice and the rights of the wider community. One view was that spiritual and cultural beliefs should only determine individual decisions: no individual or group had authority to make decisions affecting others. This belief in individual choice – but tempered by respect for the choices of others, and concern for public safety – was found among both supporters and opponents of xenotransplantation.

'Is our opposition or support for xenotransplantation as a nation going to be based on misconceived ideas or on rational thought?'

'We live in a democracy where decisions tend to reflect majority opinion – but this opinion is moderated by all sorts of minority views.'

'We have created our own problem here with our culture of pandering to the individual.'

'Cultural and spiritual views should be fully taken into account when government is making decisions about the use of xenotransplantation, as government is supposed to represent the will of the people.'

'The indigenous view of Māori cannot be voiced anywhere else in the world. As such it is vital that this worldview not only be taken into account here in Aotearoa/New Zealand, but also be given significance in terms of consideration.'

'While scientists and researchers are qualified to deal with the scientific aspects of such decisions, they cannot speak for or represent the community on spiritual or ethical matters.'

'Scientists make mistakes and will make many more ... have the scientists stopped to study the inter-generational effects?'

'Decisions made must be entirely on the merits of subject, cause and effect; not emotion, belief and superstition.'

'The Council needs to take scientific advice from a broad community of scientists and science should be the dominating factor in the decision-making process.'

'I cannot see why one person's spiritual or religious beliefs can impact on my own decisions as to what I do with my own life. Of course I defend their right to follow their own religious or spiritual or superstitious beliefs.'

However, it was usually expressed in combination with very strong statements about the need to determine the safety of xenotransplantation. Many people said individual choice only became a viable option once any public safety concerns had been resolved. (This view is discussed further in 3.4 below.)

'The individual is the only person to make the final decision. It is their body, their health issue and only they can say ye or nay within the context of their own belief system.'

'The needs of the individual should not prevail over the common good.'

3.2 Māori dialogue and deliberation

Introduction

We were struck by the range of Māori voices and viewpoints we heard. This section explores those voices and viewpoints in more detail.

The Council's discussion document proposed three scenarios that we felt might reflect possible Māori views. The more 'conservative' Māori view said that interfering with the natural order contravened te ao Māori and tikanga, and presented risks too serious to contemplate. It also said that Māori would expect the Crown, as its Treaty partner, to protect te ao Māori and heed Māori advice. A more 'liberal' view said Māori should be free to embrace and benefit from all modern scientific developments, including xenotransplantation, and that the decision to do so should rest with individuals. A third view looked at risk in Māori terms, balancing Māori priorities with Māori concerns, and said Māori should be involved collectively in decision-making.

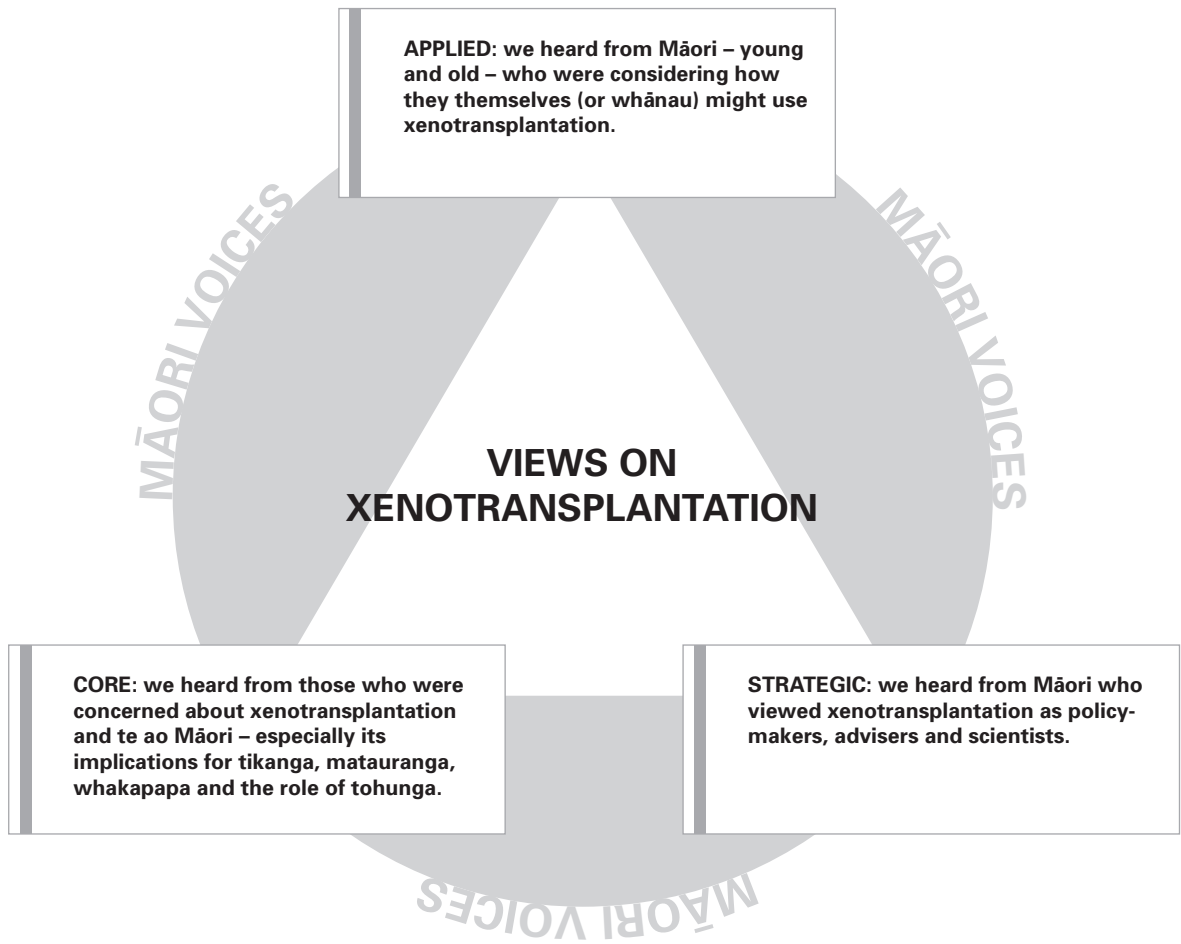
These scenarios proved a useful starting point for discussion, but the reality of Māori views was far more complex and dynamic. Indeed, it became clear throughout the dialogue that what constituted a 'Māori view' would be difficult to pinpoint with certainty.

Māori participants were young, old, kaumātua, urban professionals, scientists, health professionals, Christians, atheists and much more. There was a wide range of views on all manner of issues – from the permissibility of making individual choices that created public risks, to the responsibilities of humans for animals – and Māori voices were distributed across all these viewpoints. Moreover, viewpoints were clearly open to change throughout the dialogue process (although this phenomenon was not confined to Māori alone). One participant at a reconvened session described how she had discussed issues raised in the first session with **whānau and friends to find that [her father] had entirely altered his views on organ donation following a TV programme.** Others mentioned how some Māori had opposed blood transfusions in the past on tikanga grounds, but this had changed over time.

Acknowledging and exploring the diversity in Māori thinking is central to the Bioethics Council's role under the Treaty of Waitangi. It is part of our goal of making a place in the xenotransplantation dialogue for Māori to speak about issues as Māori. We understand that we will not hear a single, homogenous Māori voice but a multiplicity of voices – all of which are Māori.

There are two dimensions to this diversity that seem especially important. Firstly, Māori cultural, ethical and spiritual concepts can be viewed from a core, applied or strategic perspective (the terminology is borrowed from Māori research). Secondly, Māori (and other New Zealanders) may hold these views wholly or partly, and often in conjunction with other views – for example, Christian, animal rights, scientific, medico-legal and so on.

The range of Māori conceptual views we heard in the dialogue, and the relationships between them, are shown in the following diagram:



Examples of comments that characterised each conceptual viewpoint:

Core	<p><i>‘If whakapapa links are debased through xenotransplantation then Māori culture and society are affected and will have no sense of identity and connection. Whakapapa is essential to Māori and to compromise our beliefs on whakapapa will compromise our relationship within our culture and society.’</i></p> <p><i>‘To tamper with the mauri of an animal has direct impact on the environmental ecosystem.’</i></p>
Strategic	<p><i>‘Māori have strong beliefs about the land and nature, and since they are tangata whenua their opinions are very valuable.’</i></p> <p><i>‘The interests and choice of the individual should be considered first before any iwi, hapū or whānau.’</i></p>
Applied	<p><i>‘They should consider stem cell therapy before xeno.’</i></p> <p><i>‘My two kids would take the chance in an instant [to have xenotransplantation].’</i></p> <p><i>‘I don’t believe xenografts of any kind should proceed if there is a risk to others.’</i></p>

This selection of comments indicates the diversity and richness of ‘Māori views’. Caution, cultural confidence, an emphasis on tradition, an emphasis on science, a concern for the personal, a concern for the collective, a concern for the wider community – all these were found in varying strengths and combinations.

Throughout the dialogue events, we noticed an absence of Māori voices in the ‘core’ corner of the triangle. This seemed to us partly because our process had not successfully engaged with people likely to be knowledgeable on these issues (with some notable exceptions), and partly because thinking on many of these core concepts remains privileged (and is, perhaps, evolving). For example, we heard widely diverging views on the extent to which xenotransplantation is consistent with tikanga. Some said adamantly that it is not consistent and never will be; others that the challenges of xenotransplantation are too new for appropriate tikanga to have been developed. This in turn raised diverging views about the nature of tikanga itself, and the extent to which it is an immutable body of tradition and custom, or a spectrum of ever-changing practices.

Many of the Māori voices we heard came from the ‘applied’ corner of the triangle – people whose interest in xenotransplantation was a highly personal issue. For some of these people, xenotransplantation offered a real chance of improving Māori health (at a personal and community level) and responding to the shortage of Māori organ donors. But they too were wrestling with the implications of xenotransplantation for the Māori world view, and seeking more understanding of the ways in which tikanga and kawa could validate the technology for themselves and their whānau.

There were several Māori participants with ‘strategic’ interests in xenotransplantation. These people often expressed a sense of being ‘in the middle’ between the other two sets of voices, and able to negotiate between them and share knowledge. Some felt they had a lack of knowledge about the fundamental Māori concepts that xenotransplantation challenges, and were hungry to know more. Those who occupied this strategic role were also aware of being at the interface between Māori and Crown viewpoints on the subject.

A note on individual and collective rights

Some Māori had a very different understanding of individual rights and risks compared with that of other New Zealanders. To them, the concept of ‘individual’ rights extended not only to individual people, but also to whānau, hapū and iwi who they felt had rights to make decisions on behalf of their individual members within their own area.

However, other Māori attached less importance to collective decision-making and rights, believing that while whānau or hapū may influence the individual, the ultimate decision is a personal matter.

3.3 The interests of animals

Introduction

Animals are central to xenotransplantation therapies and research – as sources of cells, tissues or organs, and as recipients in animal-to-animal trials.

Currently, they are chiefly used in clinical trials and as sources of cells and tissues. Animal-to-human trials involving animal external therapies (such as the use of pig liver cells in dialysis-type processes for patients with liver failure) have been conducted in the USA and Europe. So too have animal-to-human trials of animal cell therapies, such as the implantation of neural cells from foetal pigs into the brains of patients with Parkinson’s disease.

Transplanting entire animal organs into humans still presents many problems, due to rejection by the recipient’s immune system. Some overseas studies are underway involving animal-to-animal transplants. These are exploring ways to overcome severe forms of immune rejection, and may eventually lead to the testing of animal-to-human transplants. However, all attempts at animal-to-human transplants of whole organs have so far failed.

Genetic modification of source animals is proposed by some as the most effective way of overcoming the immune rejection problem. This would involve inserting some human genes into the animals to

make their cells, tissues or organs more compatible with humans, or deleting genes that cause the severe immune reaction in humans.

To date, pigs have been preferred for xenotransplantation due to their anatomical similarity to humans and ease of breeding. However, evidence has emerged about the possibility of cross-species infections from pigs. Other animals that have been identified as potentially suitable for use in animal-to-animal studies (as transplant recipients and for cellular transplants) include mice, rats, rabbits, fish and cattle. Non-human primates are not generally regarded as suitable source animals. This is due to both the risk of infection, and ethical concerns about using highly intelligent species that are closely related to human beings.

The United States bans the use of all non-human primates in animal-to-human xenotransplantation. New Zealand law provides special protection to non-human hominids, permitting them to be used in research, testing or teaching only when it is in the best interests of the particular animal or their species. However, the 'non-human hominid' category does not include monkeys (both old world and new world) and prosimians (such as lemurs, lorises and tarsiers).

Animal welfare and ethics

Views of the animal/human relationship reflected both a 'stewardship' position (humans have a responsibility to care for other species) and a 'dominionist' position (humans have authority over all other forms of life).

Within the stewardship view was a range of opinions about the use of animals in xenotransplantation – from those who believed it was never acceptable to use animals, regardless of the benefits to humans, to those who believed using animals was acceptable if it benefited human beings and providing every step was taken to mitigate suffering.

We heard from those who believed that depriving an animal of its life or inflicting suffering for any reason – including to provide food – was unacceptable. Vegans and vegetarians were among the advocates for this position. On the other hand, we also heard the argument that if society already uses animals as a food source, how could it not use them for so important a purpose as saving human life or reducing suffering?

Some people compared the use of animals in xenotransplantation with their use in food production, saying that the end goal of xenotransplantation – to save lives and reduce human suffering – was of greater value than the production of food. Others felt that animals used for medical research or therapies suffered far more than those slaughtered for food.

'We have a moral and religious duty to research potential medical treatments, but to do so in ways that aren't oppressive or marginalizing of others, including the wider natural world.'

'I really object to the attitude that the human race has the right to use other life forms in whatever way we choose, to treat them as a "product", without any consideration for the right to live as their species has evolved to live.'

'No animals should be used unless there is good reason to expect significant benefit otherwise unattainable.'

'I am a vegetarian and a Christian, and believe that everything and everyone should be treated equally.'

'Taking a pig's life to heal a person is no worse than taking a pig's life for a BBQ.'

'As long as we are prepared to kill animals to eat, it seems difficult to argue that we should not kill them for medical purposes.'

'Animals are being treated as machines and raised in very cruel conditions. Xenotransplantation is a further moral slide.'

'If people actually saw the full effects and processes required for medical experimentation ... I suspect their views would be severely challenged.'

Even among the dominionists who saw humans as the rightful ‘masters’ of all other forms of life, we never heard it said that needless animal suffering was acceptable – only that animal suffering was less important than the suffering of fellow humans. We heard some people distinguish between animals involved in research and those used as source animals. There were worries that the former might be subject to greater suffering, especially while xenotransplantation remained in its experimental stages.

Strong concerns were expressed by some about the adequacy of New Zealand’s animal welfare legislation, and especially the work of institutional animal ethics committees.

There was a view that the existing framework for protecting animals involved in medical research was inadequate. Although this concern extended well beyond the field of xenotransplantation, for many people it represented a significant objection to xenotransplantation. Among their concerns was what they described as a lack of transparency in the way ethics committees work. They said that the identity of members was unknown to the public, their decisions could not be scrutinised, and the committees were insufficiently independent of researchers.

However, we also heard from supporters and representatives of those ethics committees. They argued strongly that their work was transparent and well-controlled, that the committees had lay members, and that there were sound personal safety reasons for not publishing their identities.

For some people, the welfare of animals and the extent of human need were inter-connected. Some said the mere possibility that xenotransplantation could meet serious health needs compelled animals to be used in research, while others believed animals should never be used, however urgent the human needs. In between these viewpoints were others which said that animals should be used if human needs were sufficiently widespread or desperate.

‘Animals use other animals to survive, that’s what we do. The desire to live and the sacrifice of other animals to do so isn’t a morbid struggle for immortality, it’s just the way evolution brought us all up.’

‘I believe we should treat animals humanely ... but I do believe that a human life is worth more ...’

‘I hope that there are some strict rules and regulations put in place, and enforced somehow to prevent possible abuse of this power we humans have.’

‘We support a moratorium on xenotransplantation pending an urgent review of Part 6 of the Animal Welfare Act 1999.’

‘Examples exist of researchers proceeding with studies despite the absence of Animal Ethics Committee approval, disease outbreaks, unexplained deaths and severe suffering ... deficiencies in the current monitoring and enforcement provisions is a real concern.’

‘It’s not that animal welfarists are opposed to finding a cure for diabetes per se; what they oppose is performing research under the present animal welfare legislation because protections for the subjects of experiments are virtually non-existent.’

‘Comments made at a Bioethics Council discussion in Auckland by a vet ... indicate that research animals are treated with the highest degree of humaneness and respect, whereas our farming practices fall woefully short of the standards expected of research laboratories.’

‘My family has a genetic predisposition to arthritis, diabetes and heart problems but I would not countenance animals dying or being used to save either my life or any family member.’

‘They should consider the number of animals who will be harmed in relation to how people will be helped.’

‘Go to your local hospital and spend a few hours in the ward with the diabetics, those young and old who are going blind, losing vital organs and limbs, or going onto dialysis ... tell me then if a pig’s life is worth more than helping those people.’

Animals likely to be used in xenotransplantation

There was an overwhelming rejection of the possible use of any kind of primates in xenotransplantation – in research, or as source animals.

We also heard the use of ‘companion animals’ emphatically rejected by some. However, we noticed some divergence in what this term meant to people. To some, the definition seemed to cover certain kinds of domestic pets but not necessarily rats or mice. Others used it to describe animals that might be regarded by some people as farm animals.

People emphasised that it was important for the animals used in xenotransplantation to be healthy and raised in conditions that ensured they were not exposed to contamination or disease.

Some people believed that all animals were unsuitable because of their fundamental physiological differences from humans. They felt animals’ lives and welfare were being compromised unnecessarily because of the mistaken belief that trialling xenotransplantation on animals gave insights into its efficacy for humans.

The fact that the animals likely to be used for xenotransplantation were all introduced species presented problems for some Māori. Some felt that tikanga has the ability to connect humans and animals quite satisfactorily by means of karakia, and through the leadership and knowledge of kaumātua. However, they said non-indigenous animals, such as pigs, were outside the human-animal relationships that tikanga has developed to deal with. There was conjecture about whether the use of a species such as paua would be any more acceptable than pigs or sheep to Māori opposed to xenotransplantation.

Genetic modification of animals

Although there was not a lot of discussion of this subject, we heard some opposition to the genetic modification of animals to make them more suitable as xenotransplant donors. Some people believed this caused unnecessary suffering to the animals through unanticipated side-effects. Others were opposed on ‘species integrity’ grounds – that the insertion of human genes into potential source animals made them in some way ‘human’ and fundamentally altered their essential characteristics. We also heard the view that xenotransplantation might be used as a covert means to introduce genetic modification more widely and make it more acceptable.

‘Non-human primates should not be used ... their complexity and capacity to suffer is greater than many other animals.’

‘We should use animals that suit our DNA and anatomy, so pigs are a good option. We should not use outrageous animals like a rat.’

‘Animals should be bred specifically for xenotransplantation so they are healthy and disease free.’

‘Different animals have different immune reactions ... results from experiments on animals cannot be used to predict results for humans.’

‘Xenotransplantation with a paua may be more readily processed in Māori terms than xenotransplantation with a pig.’

‘To tamper with the mauri of an animal has a direct impact on the environmental ecosystem.’

But we also heard from those who saw great promise in the prospect of whole organ transplantation. To these people, genetic modification of animals was permissible if it made organ transplants a possibility.

'I accept that some animals may have to be genetically altered for xeno to work.'

3.4 Individual rights and public risk

Introduction

Risks that have been associated with xenotransplantation include not only risks to the recipients themselves from the failure of a xenograft but also to the wider public from cross-species infection – for instance, through the transmission of endogenous retroviruses. At worst, these risks could lead to a widespread outbreak of serious disease.

Several ways of managing the risks have been proposed internationally: raising source animals in pathogen-free environments, requiring subjects of trials and xenograft recipients to be closely monitored and restricting their movements, and requiring them to undergo regular compulsory testing. Such measures – while not dissimilar from the public health measures used to control the spread of communicable diseases – raise a wide range of ethical and legal issues. Are the constraints on individual rights justified by the degree of public risk? How could compliance be ensured? Would such measures actually work?

There are also important questions about managing the risks associated with xenotourists: New Zealanders who return to this country after undergoing xenotransplantation overseas, and visitors from other countries who have had xenotransplantation. This is an issue requiring urgent attention. It is known that New Zealanders have already undergone xenotransplantation in other countries, some of which may not have the same public health and safety regulations or standards that we have here. We have no way of knowing how many people who have undergone xenotransplantation may have already traveled to New Zealand.

Compulsory monitoring the movements of people who have undergone xenotransplantation in the interests of public health appears to breach individual rights: the rights to privacy and confidentiality, to refuse medical treatment, and to freedom of movement. A restriction on rights might also need to be extended to non-consenting third parties (such as health workers and family members) who have also been exposed to the risks associated with xenotransplantation.

It has been suggested that the public health risks presented by xenotourism can only be managed through a coordinated global response. This might involve New Zealand becoming part of an international agreement or adopting international regulations covering the movement, monitoring and registering of xenotransplant recipients.

Perceptions of public safety and risk

We heard consistently that for xenotransplantation to be allowed, questions of safety would have to be satisfactorily resolved first. In other words, people wanted a competent and reliable medical authority to first declare that xenotransplantation did not present a significant risk to public health, and that any possible risks could be successfully managed. Only with this reassurance could further discussion take place about the mechanisms for managing public health risks.

'All types of xenotransplantation should be banned until we have more facts.'

'Safety issues are firstly a matter for expert scientific evaluation by scientists, and once we have that clarified to the extent it can be ... then the wider community, and government will be better able to respond to safety as an ethical and a regulatory consideration.'

'The fact that there is, as yet, no evidence of harm... cannot be used to argue that infection is not a possibility.'

A different view was expressed by some, especially those personally affected by conditions which may be assisted by xenotransplantation. They felt there was already enough evidence to allay concerns about public safety, and they should have access to these therapies immediately. However, others who stood to benefit personally from xenotransplantation urged caution until safety concerns relating to cross-infection risks were better understood.

Others distinguished between xenotransplantation research and the therapy itself. Some thought that even if xenotransplantation proved too risky to permit, this could only be known by allowing research to proceed. Concerns were expressed about the safety of people participating in xenotransplantation trials. Some spoke of overseas trials where people were required to consent to restrictions – including, in at least one case, agreeing not to have children.

For some people, the debate over xenotransplantation was proof of a society that had become too risk averse. This view was often expressed by people who felt the compelling human need for xenotransplantation outweighed any concerns about its safety. Some felt that New Zealand medical research – and New Zealanders with health problems – were being unnecessarily held back by an overly cautious attitude to xenotransplantation.

Restrictions on xenograft recipients

Attitudes ranged widely. Some people felt strongly that those who had undergone xenotransplantation should be publicly identified, placed in quarantine or even sterilized. While some of these proposals seemed draconian, proponents felt they were justified because of the high level of risk xenotransplantation presented.

'[If] there are already people with pig cells in them around the world, why the sudden scare-mongering?'

'The experience of many overseas islet cell transplants, skin grafts and other xenotransplants indicates that the technology is much less uncertain and less experimental than is sometimes suggested.'

'The potential good, and reduction in human suffering that could come from a breakthrough in this area is enormous – but we will never know unless the research is undertaken. Are the spiritual, ethical and cultural arguments against xenotransplantation great enough to prevent any further research in New Zealand?'

'The government should allow controlled trials of animal to human transplants as soon as possible.'

'If we'd ever let the fact of there being potential for something bad to happen stop us advancing science and technology ... we'd all be sitting out in front of our caves congratulating ourselves on banning fire because someone might get hurt or the forest burnt down.'

'If approved and proven treatments do arise from the ongoing research overseas, then New Zealanders will be at the back of a very long queue for it.'

'A xenotransplant recipient would be like a faulty unexploded bomb, a risk to themselves, their family and associates.'

'Solitary confinement after treatment, warnings to hospital staff, travel ban.'

'My suggestion is you mark everyone who receives this technology with a tattoo or nose ring or something. That way, we will have the chance to tell our whānau, tamariki, mokopuna how to look after themselves, how to protect our sacred DNA ...'

'They should agree to lifelong monitoring.'

'It should be displayed that someone has had a xenotransplantation, such as with a bracelet or on a drivers licence.'

'Patients and close contacts of the patient should be monitored, possibly for a lifetime or into succeeding generations.'

Others expressed doubts about people's willingness to comply with any notifiability or surveillance regime and the ability of the authorities to enforce compliance. Moreover, some people felt any such regime would be wrong because it would erode individual rights.

Xenotourism

We were told that xenotourism is inevitable: it will occur, and already has. People called for an effective regime to be put in place for managing the risks to New Zealanders.

Some said the rise of xenotourism was itself a justification for allowing xenotransplantation research and treatment in New Zealand. They felt it was preferable for people who wanted xenotransplantation to have it here, in a well-regulated and relatively safe environment, rather than undergo risky procedures in other countries. Others felt that xenotourism was simply unstoppable, and it was just too hard for New Zealand to introduce any measures to manage or control it. Some again questioned the likelihood of people complying with such a regime.

However, we also heard strong support for New Zealand joining forces with other countries on an international agreement about the regulation of xenotourism. Otherwise, we heard, any steps that New Zealand took independently would be irrelevant. There was reference to a role for an international authority such as the World Health Organization.

'There could never be adequate policing of any restrictions.'

'New Zealand is not adequately resourced ... to establish and enforce the surveillance systems that would be required to protect community health once clinical trials are begun.'

'If the consent process for xenotransplantation is extended beyond the individual, the question becomes; where would the consent process end?'

'Human rights is an issue, but do individuals have the right to expose the public to possible risks?'

'If there is a serious concern, why has the Government not shown greater interest in the ongoing health of New Zealanders who have already received xenotransplantation?'

'Once another country accepts [xenotransplantation] treatment it will be immaterial what we have decided in this country.'

'Actively coordinate with other countries to establish a worldwide monitoring and surveillance system.'

4. The Bioethics Council's thinking

In considering the very wide range of views we heard, we are mindful of the need for practical decisions in the area of xenotransplantation. Our thinking needs to result in recommendations about the nature and scope of new legal provisions, and changes in or to the regulatory structure. Our deliberations have also been shaped by the knowledge that we are not operating in a vacuum. Xenotransplantation is well advanced in many countries: it is with us already, whether we like it or not.

This wider context shaped the public dialogue, and also our own thinking about the cultural, ethical and spiritual dimensions of xenotransplantation – which we believe are inseparable from matters of safety. These deliberations are the focus of this section.

4.1 Cultural, ethical and spiritual factors

New Zealanders' cultural, ethical and spiritual beliefs are far from homogenous, even within groups that might be imagined to share common interests. They are complex, diverse, developing, sometimes reluctantly articulated and often in conflict – within society and within individuals.

However, we believe the following cultural, ethical and spiritual factors are particularly important to New Zealanders, and to the question of whether xenotransplantation should be allowed to proceed.

The need to respond compassionately to the suffering of people and animals

We heard passionate and compelling arguments from people for whom xenotransplantation was not just an abstract issue, but literally a life and death matter. For certain debilitating and life-threatening conditions, xenotransplantation offers hope of cure or relief from suffering. From the people suffering from such conditions, or whose loved ones are affected, the overwhelming message was: we want the option of this technology and we want it now. This view was also heard from people with no personal stake in seeing xenotransplantation proceed.

We recognise that without access to xenotransplantation some people might die; with it, some might live. Some alternative approaches – such as stem cell therapy – might also offer answers, but this is not yet known. Preventative health measures will not successfully tackle some of the health problems that xenotransplantation could potentially treat – some conditions (such as Type 1 diabetes and Huntington's disease) are not preventable, and prevention messages will be too late for many sufferers of other conditions. Given this uncertainty surrounding the alternatives to xenotransplantation, it remains a legitimate option worth exploring.

The implications of responding compassionately to the suffering of animals are more complex. For some, it implies that xenotransplantation should never be allowed, because it requires animals to experience a degree of suffering. However, refusing to use animals would have far-reaching consequences for the more general use of animals in medical research and for food production. These issues are well beyond the scope of our present work. But we do believe that compassion for the suffering of animals requires us to seek stringent controls over the welfare of animals that might be used in xenotransplantation research or therapies.

Regard for the sanctity of human life

The sanctity of life is one of the core principles underpinning New Zealand society, and indeed humanity as a whole. Regard for life, like a compassionate response to suffering, speaks in favour of helping those with serious medical conditions, and so – to the extent that xenotransplantation might help such people – it speaks in favour of permitting xenotransplantation. On the other hand, the sanctity of life and compassion also speak against imposing the risk of disease on people, and so – to the extent that xenotransplantation does this – they speak against xenotransplantation.

Clearly, the value that society attaches to human life requires that we consider very closely the safety issues presented by xenotransplantation. Some forms of xenotransplantation – such as the transplant of whole organs from primates – undoubtedly present risks that are potentially very serious, both to the individuals who undergo them and to the wider community. Other forms are less risky, if not wholly without risk. We discuss safety issues further below.

Freedom of choice

As in many areas, our individual freedom to make choices about xenotransplantation rubs against the freedoms of others. We may elect to have a xenograft ourselves, but what of the potential risks of spreading disease to countless others who have no such choice? We may find the idea of xenotransplantation offensive, but what of the diabetic who would choose it in an instant to avoid a lifetime of insulin injections? Is it right for one person's choice to deny another the chance of a better life?

One view is that freedom of choice does not extend to the creation of public risk. That view could be used to justify a complete ban on xenotransplantation. However, as a society, we are prepared to tolerate many activities that pose risks for third parties – such as importing goods from overseas, despite the biosecurity implications – providing those risks are managed and minimised.

The question of personal identity – what it means to be human – is also linked to freedom of choice. In choosing to receive xenotransplantation, would people become somehow 'less than human'? We heard through the dialogue that people felt very differently about this question – from fearing their fundamental humanity would be compromised, to believing that their identity would be positively enhanced by xenotransplantation.

In our view, how people feel about themselves as a result of xenotransplantation is an intensely personal and psychological issue. However, we believe the question of how other people might perceive, discriminate against or stigmatise those who have undergone xenotransplantation is important. Consideration needs to be given to addressing this issue in human rights legislation.

Kaitiakitanga and stewardship for the earth and its life forms

Our 2004 dialogue with the public on the use of human genes in other organisms revealed strong beliefs about the interconnectedness of human life, other species, and the physical environment. Linked to this was an understanding that humans have certain responsibilities towards other forms of life: to protect the integrity of other species, to avoid using them in ways which caused suffering or the destruction of life, to safeguard other species out of concern for both their future survival and ours. For some people, these beliefs were part of an explicitly religious or spiritual world view; they were also closely linked with the Māori concept of *kaitiakitanga*, or guardianship.

These same ideas are important in our thinking about xenotransplantation. The different forms of this technology depend heavily on animals for research and as potential sources of cells, tissues or organs. We believe human beings have a duty of care towards these animals.

Safety

The question of whether xenotransplantation is safe remains unanswered. Different procedures involve different levels of risk, and there is still a great deal to be known about all of them.

So far, the risks that have been associated with xenotransplantation include not only the failure of therapies or transplants, but also the possibility of cross-species infection. Thus, risks to individual safety may also be risks to public safety, with the worst-case scenario being a previously unknown animal infection spreading rapidly throughout the community and reaching epidemic proportions. **Although** no such cross-species infections have been reported overseas to date, the potential consequences are so serious it would be irresponsible to ignore the risk. **We therefore share the sense of caution we heard**

from many people (including enthusiastic proponents of xenotransplantation) for whom support for xenotransplantation was conditional on assurances of its safety.

Some New Zealanders have already undergone xenotransplantation in other countries. This has been seen as justification for allowing it to proceed here: perhaps it is better for New Zealanders to undergo xenotransplantation in a well-regulated environment here than in other countries where the risk to life may be greater?

However, we found this ‘inevitability’ argument to be speculative. The size of the risk depends on the type of xenotransplantation that would be done in New Zealand, and on how many New Zealanders would use it if it were available here compared with the number who would use xenotransplantation overseas. These are unknowns. So, if xenotransplantation were to be allowed here, we cannot be certain that the risk would be lower for the New Zealand public if people had treatment here rather than overseas.

The ethical question about safety and xenotransplantation cannot be avoided. As we heard, the way people think about xenotransplantation and safety is deeply entwined with their ethical beliefs. Thinking about safety also means considering whether the compelling need to save a life outweighs possible risks to individual or community safety. It means asking whether it is right to restrict the freedoms and privacy of xenograft recipients in the interests of public health. It means considering whether it is right to make individual choices that impose risks on third parties who have not made those choices.

As a country we permit many activities that pose safety risks. We encourage tourism, despite the ease with which jet travel allows the spread of communicable diseases. We allow imports of products from overseas, despite known biosecurity risks. In these cases and others, society is prepared to allow activities that impose a degree of risk providing the risks are minimised and managed in accordance with sound regulations and policy.

Moreover, because xenotransplantation involves a number of diverse and rapidly developing technologies, new information about its safety and efficacy is continually emerging. In our view, this fluid situation means that safety grounds are currently insufficient to justify an outright prohibition on xenotransplantation.

What seems more suitable is a case-by-case approach to xenotransplantation – providing it was subject to stringent and enforceable regulations, and administered by a competent organisational and regulatory framework capable of assessing and managing the particular risks associated with each individual case. This case-by-case approach could mean that some of the riskier forms – even, perhaps, all xenotransplantation – might not be allowed to proceed.

Summary

In thinking through these cultural, ethical and spiritual factors, we found nothing that justified a complete prohibition on xenotransplantation, given the compelling human need arguments. But nor were we led to think that xenotransplantation should be allowed to develop completely unfettered.

Xenotransplantation could offer some New Zealanders the chance to suffer less, and perhaps even allow some to live who would otherwise face the prospect of premature death. We do not believe they should be denied that opportunity.

However, xenotransplantation raises health risks that are yet to be adequately quantified and understood. Its development must take place within a regulatory and decision-making framework that is capable of adequately managing those risks, and whose decisions about xenotransplantation applications take into account cultural, ethical and spiritual factors – as well as the risks. Those decisions must also reflect the Treaty relationship between Crown and Māori – at the very least, by ensuring a Māori presence on xenotransplantation decision-making and monitoring bodies.

We believe that xenotransplantation decisions must be made on a case-by-case basis. Xenotransplantation takes many different forms, each involving different safety issues and levels of risks. New information

about technologies and possible risks is emerging constantly. In this context, case-by-case decision-making is the right response. We note that in some instances, this may mean some applications or some specific forms of xenotransplantation are not allowed to proceed.

We also note that it can be very difficult to find consensus about cultural, ethical and spiritual factors at an abstract level. Yet our experience has been that when those factors are brought to bear on specific cases or decisions, agreement is much more likely. Again, case-by-case decision-making is the appropriate course of action.

Therefore, the Bioethics Council recommends that:

Recommendation 1

Xenotransplantation (animal-to-human, animal-to-animal) be allowed to develop in New Zealand, with that development being demonstrably shaped by:

- the resolution and management of safety issues by a competent authority
- the Treaty relationship between Crown and Māori
- cultural, ethical and spiritual factors that matter to New Zealanders, including a compassionate response to the suffering of people and animals; the sanctity of human life; freedom of choice; kaitiaticanga and stewardship for other life forms; and safety.

In considering how this recommendation could be put into effect, we note the existing regulatory and decision-making framework of animal and human ethics committees for dealing with ethical issues associated with biotechnology. This framework may or may not be adequate to deal with xenotransplantation – a biotechnology which does, we believe, raise distinctive issues. For example, xenotransplantation research raises the question of whether participants in xenotransplantation trials should be required to waive the usual right to confidentiality, and the freedom to withdraw from trials at will.

It may be appropriate to establish a specialised xenotransplantation committee (as the United Kingdom has done), charged with considering cultural, ethical, spiritual and safety issues. Alternatively, the functions, expertise and resources of the existing bodies could be developed and expanded so that they are equipped to manage the specific challenges of xenotransplantation. In either case, as this is a developing technology, it is important for an appropriate monitoring regime to oversee both the adequacy of the regulatory/decision-making framework and developments in the technology itself.

We note that there is currently no legal mechanism that requires researchers to submit their research to a human ethics committee. It is important that this gap be filled in the case of xenotransplantation research.

Therefore, the Bioethics Council recommends that:

Recommendation 2

The Government implements an appropriate regulatory and decision-making framework to guide the development of xenotransplantation. This might involve the establishment of a specialist body, or the further development of the existing framework.

Recommendation 3

Consistent with the framework chosen, decision-making bodies be guided by national standards and have access to expertise. Both must be adequate to deal with the special challenges of xenotransplantation – including its cultural, ethical and spiritual dimensions.

Recommendation 4

All xenotransplantation research involving human subjects be legally obliged to comply with the requirements of the regulatory framework.

Recommendation 5

The Government puts in place a monitoring body to oversee the development of the regulatory and decision-making framework, and developments in xenotransplantation technology.

4.2 Māori and xenotransplantation

Many Māori believe xenotransplantation has much to offer, in terms of addressing the health needs of Māori and the shortage of Māori organ donors. For some, this ‘human need’ argument is sufficient, and negates any cultural, ethical and spiritual concerns. Others – while recognising the human need – are troubled by the fact that xenotransplantation does not appear to be validated by Tikanga Māori and the wider Māori world view. They are actively seeking guidance about whether the two can be reconciled and, if so, how. Still others say that the Māori world view and tikanga do not – and never will – accommodate xenotransplantation.

We believe a possible way forward is for Māori to be encouraged to examine or develop the fundamental tikanga and mataraunga they need to make decisions about xenotransplantation. It is only by having an adequate frame of reference and knowledge base that Māori can determine if and how they participate in xenotransplantation, individually and collectively.

At the moment, that frame of reference does not appear adequate. Developing it would require the involvement of participants we did not hear from extensively in our dialogue process – tohunga who might advance Māori knowledge, including by providing new karakia; kaumatua to discuss new ideas with hapū and iwi; people with knowledge of wider Polynesian spiritual concepts and understandings that might enrich fundamental Māori concepts. They would join the many other Māori who have already become involved in the xenotransplantation dialogue as scientists, policy-makers and potential users.

To be effective, this dialogue or wananga needs to be an intra-cultural process, called by a person of status within the Māori world. While Government and government agencies (including the Bioethics Council) might have a part to play in terms of providing information and support, it would be primarily an enabling role rather than a prescriptive or leading one. The outcomes of this wananga would need to be carefully considered in the context of Tikanga Māori: who do those outcomes ‘belong’ to, how would they be promulgated and by whom?

The Bioethics Council believes this intra-cultural dialogue is essential to enable Māori to be part of decision-making on xenotransplantation, and is willing to provide further advice to the Minister for the Environment about how this could be achieved.

Therefore, the Bioethics Council recommends that:

Recommendation 6

- (a) The Minister for the Environment enables, including through the provision of funding, an intra-cultural dialogue process (wananga) for Māori to examine their knowledge base from which to engage with xenotransplantation and other forms of biotechnology. This would address tikanga and spiritual, ethical and cultural issues within te ao Māori, including whakapapa, karakia etc.
- (b) Subject to tikanga, the knowledge/matauranga emerging from this intra-cultural dialogue be widely promulgated.

4.3 The interests of animals

The Bioethics Council considers there are significant ethical issues relating to the welfare of animals used in xenotransplantation – either in research and trials, or as sources of cells and organs.

Some in the community question whether it is right for animals ever to be used to benefit humans. This is an important question but, as we have already said in relation to the need for a compassionate response to the suffering of animals, it is too far-reaching to consider in our present deliberations about xenotransplantation.

However, we do believe it is important that when animals are used to benefit humans, they do not experience undue suffering. This view came through very strongly in many submissions, which supported xenotransplantation only if it involved no needless cruelty to animals.

This sense that humans have a ‘duty of care’ towards animals guides our thinking on two aspects of xenotransplantation: the work of institutional animal ethics committees, and the adequacy of present legislation governing the use of animals.

Animal ethics committee

Throughout the dialogue process, we heard questions about the adequacy of our animal ethics committees to safeguard the welfare of animals used in research. Particular concerns included the independence of such committees; their composition, decision-making processes and standards; how transparently they operate; and the availability of information. While this disquiet extends beyond xenotransplantation research alone, we think it is important to acknowledge concerns about the work of institutional animal ethics committees.

While we appreciate their committee members’ desire for some degree of confidentiality, and accept the need for anonymity out of concern for the personal safety of members, we feel that this is contributing to something of a ‘standoff’ between the committees and the public. This may be impeding the development of a more productive relationship that could work to the benefit of all, including animals.

While we make no specific recommendation, the Bioethics Council will be drawing this issue (which is wider than xenotransplantation alone) to the attention of the minister responsible for animal ethics committees.

Animal welfare legislation

The present Animal Welfare Act 1999 offers special protection to non-human hominids, saying they can be used in research, testing or teaching only when it is in the best interests of the particular animal or their species. However, the ‘non-human hominid’ category does not include monkeys (both old world and new world) and prosimians (lemurs, lorises etc). It would probably come as a surprise to many

New Zealanders to find that monkeys, for example, are not specifically protected by our animal welfare legislation.

We believe that the Act's special protection should be extended to protect all primates from being used in xenotransplantation research or therapy. Primates are highly intelligent, and very close to humans in their social organisation and behaviours. As such, they have a special moral status that means they should not be used in xenotransplantation research or as source animals.

Therefore, the Bioethics Council recommends that:

Recommendation 7

The special protection afforded by the Animal Welfare Act 1999 to non-human hominids be extended to include all members of the order Primates.

4.4 Xenograft recipients and public health

The main safety concern at present is posed by xenotourism – New Zealanders returning home after travelling overseas for xenografts, and visitors to New Zealand who have had xenografts. What should be done about xenotourism is a question that arises whether or not xenotransplantation is permitted in New Zealand.

We believe there is a strong public health argument for having some kind of notifiability or registration regime to cover xenograft recipients. However, we do not support the somewhat draconian measures – public identification of recipients, quarantine, compulsory monitoring – which some people have advocated. We do not believe that the risk to the community warrants a response that places such a burden on the individual, and that potentially exposes them to stigmatisation and discrimination. Moreover, such regimes are likely to be actually counter-productive to public health by discouraging xenograft recipients from seeking medical care or advice in order to avoid detection.

A national register of all people in New Zealand, residents and visitors alike, who have undergone xenotransplantation would be one solution. Traceability would be the main aim. In the event of any outbreak of diseases that might be linked to xenotransplantation, those on the register could be readily contacted and offered access to medical treatment and information – both for their own sake and the sake of the wider community.

New Zealanders having xenografts in New Zealand at some future time would need to be placed on the register by the medical practitioner concerned. Medical practitioners conducting xenotransplantation research on human subjects would also be required to place those individuals on the register. In placing the onus on medical practitioners to advise the public health authorities, we are proposing a similar approach to the present system whereby doctors must advise the Ministry of Health whenever, in their professional capacity, they encounter someone with a specified communicable disease.

Meanwhile, people entering the country from overseas (including returning New Zealanders) would be required to declare that they have had a xenotransplant and to supply the public health authorities with their address and contact details.

Such a system is more likely to encourage compliance than draconian measures, which there is good evidence for thinking would be counter-productive for public health. **Although the regime conflicts with what we normally regard as important individual rights – to confidentiality and privacy – we believe this is legitimate in the interests of public safety.** Privacy concerns could and should be mitigated by regulations covering access to and use of the information contained in the register.

The issue of possible stigmatisation and discrimination against xenograft recipients seems to us an important one. The Human Rights Commission is probably the organisation best suited to considering whether and how this issue should be addressed under human rights legislation.

A related area we also believe requires investigation is liability in the event of xenotransplantation causing a public health risk. Who would be accountable? How would costs be determined and allocated? It would be appropriate for the Law Commission to investigate this issue, in the same way that they earlier investigated liability issues in respect of genetic modification.

Therefore, the Bioethics Council recommends that:

Recommendation 8:

- (a) A register of New Zealanders and other people entering New Zealand who have undergone xenotransplantation be kept by the Ministry of Health for the purpose of traceability.
- (b) Anyone entering New Zealand who is a current or past recipient of a xenograft be required to make a declaration to this effect on the entry documentation, and that this information be entered on the register.
- (c) Medical practitioners be required to notify the Ministry of Health when they carry out a xenograft or when, in their professional capacity, they encounter a person who has undergone xenotransplantation, and that this information be entered on the register.
- (d) The Government asks the Human Rights Commission to investigate the adequacy of present human rights legislation to deal with stigmatisation and discrimination towards people who have undergone xenotransplantation.
- (e) The Government asks the Law Commission (or other appropriate body) to investigate liability issues associated with xenotransplantation.

5. Summary of recommendations

Toi te Taiao: the Bioethics Council recommends that:

Recommendation 1

Xenotransplantation (animal-to-human, animal-to-animal) be allowed to develop in New Zealand, with that development being demonstrably shaped by:

- the resolution and management of safety issues by a competent authority
- the Treaty relationship between Crown and Māori
- cultural, ethical and spiritual factors that matter to New Zealanders, including a compassionate response to the suffering of people and animals; the sanctity of human life; freedom of choice; kaitiaticanga and stewardship for other life forms; and safety.

Recommendation 2

The Government implements an appropriate regulatory and decision-making framework to guide the development of xenotransplantation. This might involve the establishment of a specialist body, or the further development of the existing framework.

Recommendation 3

Consistent with the framework chosen, decision-making bodies be guided by national standards and have access to expertise. Both must be adequate to deal with the special challenges of xenotransplantation – including its cultural, ethical and spiritual dimensions.

Recommendation 4

All xenotransplantation research involving human subjects be legally obliged to comply with the requirements of the regulatory framework.

Recommendation 5

The Government puts in place a monitoring body to oversee the development of the regulatory and decision-making framework, and developments in xenotransplantation technology.

Recommendation 6

- (a) The Minister for the Environment enables, including through the provision of funding, an intra-cultural dialogue process (wananga) for Māori to examine their knowledge base from which to engage with xenotransplantation and other forms of biotechnology. This would address tikanga and spiritual, ethical and cultural issues within te ao Māori, including whakapapa, karakia etc.
- (b) Subject to tikanga, the knowledge/matauranga emerging from this intra-cultural dialogue be widely promulgated.

Recommendation 7

The special protection afforded by the Animal Welfare Act 1999 to non-human hominids be extended to include all members of the order Primates.

Recommendation 8

- (a) A register of New Zealanders and other people entering New Zealand who have undergone xenotransplantation be kept by the Ministry of Health for the purpose of traceability.
- (b) Anyone entering New Zealand who is a current or past recipient of a xenograft be required to make a declaration to this effect on the entry documentation, and that this information be entered on the register.
- (c) Medical practitioners be required to notify the Ministry of Health when they carry out a xenograft or when, in their professional capacity, they encounter a person who has undergone xenotransplantation, and that this information be entered on the register.
- (d) The Government asks the Human Rights Commission to investigate the adequacy of present human rights legislation to deal with stigmatisation and discrimination towards people who have undergone xenotransplantation.
- (e) The Government asks the Law Commission (or other appropriate body) to investigate liability issues associated with xenotransplantation.

Appendix A: Reflections on the evaluation process

The Bioethics Council's 2004 dialogue on human genes in other organisms – its first such exercise – provided a useful platform from which to plan the xenotransplantation dialogue. We were able to learn from it what worked well and what was less successful, and to refine our processes and expectations.

The 2005 dialogue events also offer valuable lessons, both for the Council itself and for other organisations considering embarking on similar public dialogue processes. The following reflections are based on a report by Chris Nichol of Mixed Media Ltd, leader of the team of facilitators who conducted the xenotransplantation dialogue on behalf of the Council.

Numbers attending dialogue events

Auckland		
*Ritimana Kohanga Reo session 1		23
reconvened session		14
Langham Hotel session 1		28
reconvened session		16
*Parnell Community Centre session 1		3
new event		6
Central Hotel session 1		10
reconvened session		4
Palmerston North		
session 1		17
reconvened session		14
Wellington		
session 1		17
reconvened session		10
** Christchurch		
session 1		33
reconvened session		19
Dunedin		
session 1		19
reconvened session		11

* Tikanga Māori session ** open event in bicultural environment

The overall value of dialogue

Dialogue underscores diversity in the community and respect, despite difference. As a result, participants with opposing views listen to and often hear one another. The significance of this cannot be underestimated. Whereas, when carrying out their 'homework' some would only talk with people of like mind, within the context of the dialogue event itself they were bound to engage with people who had different perspectives. The lack of manifest conflict within the dialogue events testifies to the way the process enables engagement of views that would otherwise seldom interact.

Further even than this, on several occasions, alternative points of view were recognised. That is not to say they were agreed with. But the legitimacy of them being held and the good faith with which they were embraced was affirmed.

The process also helps identify common ground where there seems none, while filtering out at which point(s) people really are separated from one another. This commonality fosters community, while the clarifying of distinctions helps focus future engagement.

The dialogue series built mutual respect. In it, individuals operated, as one facilitator said, ‘out of their integrity ... out of the rangatira realm’.

Scope of the dialogue

One concern that emerged was that the focus of the dialogue was too narrow. Certainly with a very explicit subject, the potential for circularity in the discussion is always present. In addition, unless participants are empowered to recognise the legitimacy of their response to a technical subject as having the same authority as expertise, some participants can ‘dry up’.

One alternative would have been to allow more scope to be given to participants to focus the dialogue on their particular interests, allowing the direction of the event to develop over time. While this approach has some merit, it presumes a considerably longer series of events (with consequent budget implications) and the key interests of the dialogue’s sponsors may not be addressed.

Preparing people for dialogue

People participate in the event they expect. Accordingly, if they come to a dialogue event thinking it will be consultation (or an opportunity for advocacy), their expectations need to be reworked if the event is to be constructive.

The facilitation team believes it is important to take care when communicating with participants before dialogue events. Announcements, invitations, explanations, background material, all contribute to the expectation of the participant and serve to shape the frame of mind with which they engage. Dialogue is enhanced if the process is clearly signalled early and often.

Most people have never experienced structured and facilitated dialogue before, and have no reason to expect it – or even to know what to expect. There may be value in the facilitation team spending time with communications and marketing staff to see if it is possible to advance understandings before people arrive at dialogue events.

Expectations are also set by the subject matter. It became clear, as the dialogue events progressed, that the very word ‘xenotransplantation’ made many prospective participants nervous. They didn’t know what it meant or what to do with it. As a consequence, we believe many avoided it. The result was lower than expected numbers at some dialogue events.

Mainstream and Māori meetings

While there was real value in having identified Māori hui, **engagement between Māori and Pakeha** was somewhat reduced as a result. At the Auckland and Wellington mainstream meetings and also at the bicultural hui in Christchurch, which was largely populated by Pakeha, this interaction was a highlight.

An example of this came from the Christchurch meeting where a Pakeha woman suggested that most Pakeha don’t have the language to talk about their ‘gut’ reactions to xenotransplantation. For secularised Pakeha, ‘culture’ tends to mean ethnicity, ‘spirituality’ refers to something otherworldly, and ‘ethics’ is something for a specialist ethics committee. Hearing **Māori talking about cultural, ethical and spiritual** values from a position of ownership highlighted, for her, something crucial for our communities’ reflections on the cultural, ethical and spiritual dimensions of xenotransplantation.

It would be worth considering encouraging mixed groups in the future. After all, the very nature of dialogue is to bring together people of different views and different backgrounds.

We would, accordingly, recommend a stronger emphasis on events which encourage Māori and other ethnic and cultural communities to meet together and explore the diversity of their perspectives.

Having said this, there is a good case for a dialogue group built around a dedicated group of Māori who have expertise and experience in the matauranga Māori and the subject matter. There is also an argument for another Māori-only group where young and more experienced Māori may share their differing understandings.

The situation was further complicated by three hui being scheduled for Auckland. In the future, consideration could be given to scheduling Māori events in other contexts, including rural communities where there is a high Māori population base. Because of the low number of Māori who turned out, there may well be value in following the Kohanga Reo model whereby an interested person within a Māori organisation organises others to attend a hui.

Another observation was that it would have been beneficial for the facilitators of the Māori events to have met with the Māori members of the Council to help consider together how these events were to be run.

Evaluation

Evaluation of the process has been informal, and was left largely in the hands of the facilitators themselves. This is not an entirely satisfactory situation, as it does not provide for external monitoring. However, some form of monitoring of the process is vital, so that it can continue to offer participants a secure environment within which they can listen respectfully and speak with integrity.

The processes in place to enable this monitoring include:

- evaluations from participants after each event
- co-facilitators' debrief after each event
- debrief with Council members present after each event
- report from Council members to project team
- support and debrief with the other facilitation team after events
- regular contact with project management team
- meeting of representatives of facilitation team with project manager and Secretariat after first round of dialogues
- debrief as report development
- meeting of facilitation team with project manager and Secretariat after dialogues as part of report development.

The principal drawbacks of these systems are a lack of documentation and an absence of reflection that takes place 'at one remove' from participation. These difficulties could be remedied and may well help further fine-tune the process both for any present and future projects. There would, inevitably, be a cost associated with additional staffing.

Conclusion

Toi te Taiao: the Bioethics Council's dialogue on the cultural, ethical and spiritual dimensions of xenotransplantation has enabled several significant outcomes. These include:

- The further development of an effective model of short-term dialogue which enables a range of people with varying degrees of experience and expertise in the subject to engage together in a safe environment - expressing their views, listening to the perspectives of others, and discovering new possibilities together.
- The intentional reframing of this model for use within Tikanga Māori and bicultural contexts.
- Identification of consequent learnings for further development of the model.
- Provision of a wide range of views from a diverse set of New Zealand communities. This has informed the Council's subsequent considerations and the advice it provides the Minister for the Environment on the cultural, ethical and spiritual dimension of xenotransplantation.

Appendix B: Glossary of terms

A more detailed glossary of terms relating to xenotransplantation can be found in the public discussion document, *The Cultural, Spiritual and Ethical Aspects of Xenotransplantation: Animal-to-Human Transplantation*.

animal-to-human trial	<i>xenotransplantation research in which organs, cells or tissues are transferred from an animal species (such as pigs) to humans. See also clinical trial.</i>
clinical trial	<i>a research study that tests how well new medical treatments or other interventions work in people.</i>
endogenous retrovirus	<i>a retrovirus that is incorporated in the genetic material in every cell in the body of its host, and is passed down from generation to generation. Normally an endogenous retrovirus does not cause any obvious signs of disease. See also retrovirus.</i>
external therapies	<i>therapies that occur outside the patient's body, such as when blood from a patient with liver failure is passed through a machine containing live animal liver cells, to remove toxic substances (a procedure similar to kidney dialysis).</i>
hapū	<i>clan</i>
immune rejection	<i>an immunological response by a person's body when it refuses to accept substances or organisms that it recognises as foreign.</i>
iwi	<i>tribe</i>
kaitiakitanga	<i>guardianship</i>
karakia	<i>incantation, prayer, ritual</i>
kawa	<i>procedure, protocol</i>
matauranga	<i>knowledge</i>
non-human primates	<i>mammals of the primate order apart from human beings (for example, apes, baboons, monkeys).</i>
presumed consent	<i>in the context of transplantation, the principle that unless a person has specifically requested that their tissues or organs <u>not</u> be used for transplantation, their consent can be presumed.</i>
rangatira	<i>chief</i>
retrovirus	<i>a family of viruses defined by their particular genetic structure. The family includes the lentiviruses (such as human immunodeficiency virus, HIV), oncoviruses (such as human T-cell leukaemia virus) and endogenous retroviruses (which exist as sequences embedded in the genome of their host).</i>
stem cells	<i>cells with the ability to divide for indefinite periods in culture and to give rise to specialised cells.</i>
te ao Māori	<i>the Māori world view</i>
Tikanga Māori	<i>traditional customs</i>

Type 1 diabetes	<i>a condition characterised by high blood glucose levels caused by a lack of insulin. This occurs when the insulin-producing islet cells in the pancreas are not destroyed by the body's immune system. Type 1 diabetes typically develops in young people and is treated by injections of insulin. It is not related to lifestyle factors.</i>
Type 2 diabetes	<i>a condition characterised by high blood glucose levels caused by (stage 1) the body's inability to use insulin effectively and (stage 2) a lack of insulin. Type 2 diabetes usually occurs in middle-aged and older people.</i>
wananga	<i>learning process</i>
whanau	<i>family</i>
xenografts	<i>organs, tissues or cells that have been transplanted from one species to another.</i>
xenotourists	<i>recipients of xenografts who travel internationally, and who are of concern because of the potentially reduced ability to monitor their health, especially in the context of spreading a disease caused by xenotransplantation.</i>
xenotransplantation	<i>the transplantation of living cells, tissues and organs from one species to another. Xenotransplantation procedures include animal organ transplantation, animal cell therapies and animal external therapies.</i>