

Review of the Regulation of Human Tissue and Tissue-based Therapies: Meeting Report

Christchurch Hui 11 May 2004

PROCESS

This public hui was held at Ngā Hau e Wha marae, 250 Pages Rd, Christchurch from 9.30 am to 3.30 pm on Tuesday 11 May 2004. The day began with a presentation by the Ministry of Health and questions from the attendees. The presentation was followed by discussion of the following main themes from the Discussion Document:

- Options for organ and tissue donation
- Informed consent for non-therapeutic uses of tissue
- A standard for tissue management
- Other issues e.g. still-born children, import and export of tissue.

SUMMARY OF KEY ISSUES

Presumed consent

There was strong consensus that presumed consent for organ donation was unacceptable and inappropriate. The idea was seen as unfair, particularly to Māori, and frightening. However, there was little discussion around the alternative options outlined in the discussion document.

Stillborn children

The feeling of the group was that stillborn children should be extended the same protections as children born live. Some participants also felt that miscarried foetuses and earlier stages of human development should also be accorded such protections.

Organs as taonga

Organs and other parts of the body are seen as taonga in the Māori community. They are viewed as having been handed down from generation to generation, and therefore as not being the property of the individual. This idea was reflected in the frequent mention of whānau as being a proper part of the consent process, and the need for the support of the whānau for an individual's decision.

There was discussion about what the implications of organ donation might be in terms of whakapapa, wairua and māuri. Given that Māori identity is so closely linked to genealogy, what effect would transplanting organs between genealogies have? How does the life force of transplanted organs affect their recipients?

Conversations to occur in Māori communities

In order for Māori communities to be able to respond best to the issues raised in the review, they need to hold conversations among themselves. Policy makers should not pre-empt the outcomes of these conversations.

Information

Where tissue has been collected and is being stored, sound information about what it is being used for ought to be available to those from whom it was taken.

Shared humanity

Organ donation reminds us of our shared humanity and the bonds between every human being. It should be a cause for celebration where it saves lives. It should also be recognised as an act with a significant spiritual and cultural dimension that needs to be accommodated.

Meetings between donors, recipients and their families

There was a strong feeling that the gap between donors and recipients needed to be broken down so that organs could be given and received with love. There need to be mechanisms for this to happen, and for the spirituality of the procedure to be acknowledged. However, it must be possible for either party to opt not to know about the other.

Communication

The medical community must communicate honestly with the Māori community and with parents and families of children who have died.

QUESTION BY QUESTION SUMMARY

PART A: INTRODUCTION	
1.	As you go through this document and consider the many issues within it, please consider the definition of tissue on page 2 and let the Ministry know if you think the definition should be changed and why. (see page 2)
	<ul style="list-style-type: none">• One participant felt that the definition of tissue in the document was fine but that some Māori might see it differently. Some would say that organs, for example, do not count as tissue, as tissue is small parts of the body. Organisation of 'body parts' into organs and tissue did not imply a hierarchy, only perception and differences.• Tissue donation was thought to be different to organ donation.• The term 'body parts' was rejected in favour of 'organs' by some participants.• Another participant felt that there was no difference between organs and bits of organs or other tissues, as all are taonga. This compartmentalisation mentality is misguided. 'At one stage I was but one cell.'
PART B: NON-THERAPEUTIC USE OF TISSUE	
3.	Do you think that the new legislative framework should have informed consent as its foremost principle? (see pages 26-28)
	<ul style="list-style-type: none">• The biggest concerns were around abuses of consent and goalposts being moved.

	<ul style="list-style-type: none"> • Consent was seen as an ongoing, dynamic process, and not just a matter of ticking a box or signing a form. Expectations and technology change over time. So should consent. • As the medical establishment has a vested interest in obtaining tissue, they will want to ignore consent information that does not suit their purposes. There is a need for independent advocacy and mediation between families and doctors/researchers. • The idea of consent having a time limit was discussed and had general support as an option. • Some participants raised concerns about tissue being taken out of the country without people's consent. • Others were concerned at what informed consent might mean from the perspectives of iwi, hapū and whānau. • There was concern that the goalposts were shifted in this area without people knowing about it.
4.	If so, should a secondary principle recognise that in certain circumstances, the public good associated with the use of tissue will outweigh informed consent <i>provided that safeguards are in place</i>? Please explain your reasons for agreeing or disagreeing. (see pages 26-28)
	<ul style="list-style-type: none"> • One participant felt there was no excuse for informed consent not being obtained in every instance. • Discussion took place around what a 'public good' might be, and the point that safety issues might prevent tissue samples being returned was raised. • Concern was raised around the taking of genetic information in the name of the public good. • Concern was expressed at the possibility that state-owned and controlled organisations that held tissue samples could be privatised and the samples used in unethical ways.
7.	Are there any reasons why the provision in the Human Tissue Act allowing the use of unclaimed bodies for non-therapeutic purposes should be retained? (see pages 30-31)
	<ul style="list-style-type: none"> • Concerns were expressed at the possible use of the bodies of people without families/whānau for purposes they would not have consented to.
10.	Do you agree that the new legislative framework should allow tissue from deceased persons to be used for non-therapeutic purposes (other than anatomical examination) with appropriate informed consent? If not, please explain your reasons. (see pages 31-32)
	<ul style="list-style-type: none"> • A participant told of being trained by doctors from Greenlane because they were the southern hemisphere's pre-eminent heart specialists. This was largely due to their large collection of hearts. In the 1960s, parts of autopsied bodies could be kept with the permission of the superintendent of the hospital, although this changed in the 1980s. The participant did not think that the collection should be taken away. • There is a need for common sense in dealing with these issues. Tissue samples should be stored forever as destroying them goes against common sense. • One participant was appalled at the use of Guthrie blood for purposes that had not been consented to. The blood was collected for one purpose 'and that's the end of the matter'. • Concern was expressed at different hospitals having different procedures for when people die.

11.	<p>When tissue has been collected during the life of a person and is wanted for uses after that person's death for a reason where the wishes of the deceased person are not known, should the new legislation allow these uses with appropriate safeguards? If so, are the following suggested safeguards appropriate.</p> <p>a) If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.</p> <p>b) If the proposed use is a research project, or audit, the tissue could not be used unless the research had been approved by an ethics committee, or the tissue was to be used for a professionally recognised quality assurance programme, an external audit or evaluation of services that was undertaken to assure or improve the quality of services.</p> <p>Please describe any other ideas you have. (see page 32)</p>
	<ul style="list-style-type: none"> • The idea of being able to put time limits on consent was discussed and had general support as an option. • Audits of hospital collections need to be carried out to see what they contain. • Other participants expressed the view that going beyond the limits of informed consent was not acceptable in the case of new technologies.
13.	<p>Do you think that the new legislation should allow families to have the final say over the donation of tissue from their deceased loved one for non-therapeutic purposes? If not, please explain why you think the wishes of the deceased should be <i>required</i> to be followed and if there should be any exceptions to this requirement. (see page 32)</p>
	<ul style="list-style-type: none"> • Discussion on this topic centred around whānau becoming part of the consent process. • The status quo in terms of the person legally in possession of the body acting in accordance with the wishes of the family should be put into law. Next of kin must form part of the decision-making process. • What weight should consent have for couples who are not married? • There is a short timeframe for transplants to be effective.
14.	<p>Do you agree that consent from the parents or guardians should always be gained for tissue from a deceased child to be used for non-therapeutic purposes? If you don't agree, please explain why. (see pages 33-34)</p>
	<ul style="list-style-type: none"> • One participant was of the opinion that no parent would decline to consent to something good (eg education, research) coming out of their child's death. • Communication with families/whānau of deceased must be honest. • Limits of decision-making ability with regard to those with special needs must be recognised. • There was concern at situations in which parents did not know whether their child was buried whole and had no idea of how to go about finding out.
15.	<p>If a child or young person is legally competent, and their wishes in relation to the non-therapeutic uses of their tissue are known, then should the same procedures as with adults apply? If you don't agree, please explain why. (see pages 33-34)</p>
	<ul style="list-style-type: none"> • Concern was raised at 16 year olds and other young people consenting to such procedures. • Responsibility for a disabled person can change over time. The trustee of the family trust can be a different person to the primary caregiver. Who decides what

	happens after the disabled person's death?
16.	Should both parents have an equal say in what happens to the body of their deceased child, or are there circumstances where the mother's wishes should prevail? (see pages 33-34)
	<ul style="list-style-type: none"> One participant was concerned that while her son was alive, she had custody of him and made all decisions regarding his care, and yet after his death his estranged father had an equal say in what happened. Need to recognise primary caregiver in some way?
18.	Do you think that an overarching standard or code for tissue management that can be applied flexibly to different agencies is appropriate? Please explain why or why not. (see pages 35-37)
	<ul style="list-style-type: none"> Questions were asked about a possible central register of tissue held in New Zealand. How would individuals access information about held tissue?
21.	Please share your ideas on possible approaches to monitoring tissue management practices that allow for robust monitoring to take place without imposing unnecessary compliance costs on the health and disability support sector. (see pages 37-38)
	<ul style="list-style-type: none"> Need to discuss timeframe for which tissue can be kept and have an update process so people know if the situation has changed.
26.	Please tell us your ideas for removing the ambiguity created by the term 'the person in charge (of an institution)'. In the case of hospitals, which of the following three options do you prefer for the new legislation: a) a particular position within a hospital designated as the person lawfully in possession (eg, the institution's chief executive or medical director)? b) a requirement that institutions appoint or nominate for appointment a particular person from time to time? c) a particular position within the District Health Board, likely to be the chief executive, with the ability for this responsibility to be delegated as appropriate? Please share any other suggestions you have. (see pages 39-40)
	<ul style="list-style-type: none"> The fact that this part of the Human Tissue Act was outdated and confusing was discussed, but there was no discussion around options for its improvement.
27.	Do you think that stillborn children and foetuses should be brought within the coverage of the new regulatory framework? If not, please explain why. (see pages 41-42)
	<ul style="list-style-type: none"> Attendees were strongly in favour of stillborn children and foetuses being brought within the framework. One participant whose child was stillborn considered the child as much a part of her family as her other children and was appalled that stillborn children were not considered in the same way as other children. It was pointed out that stillborn children get named and therefore should be treated like live births in other ways. This idea was extended to miscarriages, and the idea that miscarried foetuses were living persons put forward to argue for their inclusion too.
32.	The implications of access to genetic information are complex and affect people beyond the individual who is the source of the information. We are seeking your thoughts on whether the coverage of the Health Information Privacy Code should be extended to specifically address genetic issues. If so, please tell us your views on any or all of the issues listed above. (see pages 47-50)

	<ul style="list-style-type: none"> • Discussion of genetic privacy centred around the concern that tissue collected for another purpose could be used for collecting genetic information.
33.	<p>Following the passage of the Health (National Cervical Screening Programme) Amendment Act, changes are able to be made to the Health (Retention of Health Information) Regulations 1996 to cover the retention of specimens as well as other health information.</p> <p>The Ministry is proposing that the following changes be made to the regulations:</p> <ol style="list-style-type: none"> the definition of a ‘specimen’, beyond ‘a bodily sample or tissue sample taken from a person’, should be covered by the regulations (ie, the sorts of specimens the regulations should apply to) the purposes for which different sorts of specimens should be retained the minimum period or periods for which specimens should be retained and any particular period for which particular specimens should be retained particular storage conditions that may be required for specimens (including whether different arrangements are needed for different types of specimens), and the practical issues that arise from any storage requirements the implications for specimens of health information being able to be returned to the individual concerned ways that the regulations can be designed to anticipate future developments in technology the management of health information (including specimens) when a provider ceases to practise or be in business. <p>Are there matters in addition to those listed above that you think need to be considered when changes are made to the regulations? Please explain your suggestions and share your initial thoughts about what should be covered by the regulations in relation to these issues. (see pages 50-53)</p>
	<ul style="list-style-type: none"> • One participant thought that common sense should prevail in retention of tissue samples. They should be kept forever, instead of having time limits on their storage. • Concern was expressed at the possibility that the government could sell off an organisation which held tissue samples, and that the new owners could use that tissue for purposes that had not been consented to.

PART C: THERAPEUTIC USE OF TISSUE

34.	<p>The new legislative framework could consider five options (with combinations) to consent for organ and tissue donation. Of the options below, please tell us which you think may be better and why. The options are:</p> <ol style="list-style-type: none"> presumed consent requirement for wishes to be followed requirement to state wishes requirement to request status quo. (see pages 61-69)
	<ul style="list-style-type: none"> • There was strong agreement that presumed consent was not appropriate or acceptable. • Contestability (eg through court system) would be a problem. • More safeguards would be required in case of presumed consent, as many people would not understand the process of opting-out. • Although the cervical screening programme automatically opts women in, most Māori women do not know they are a part of it. This argues against using

	<p>presumed consent for organ donation.</p> <ul style="list-style-type: none"> • Presumed consent was equated with organ harvesting, and the problem of how to tell everyone that they might need to opt-out was raised. • In what sort of a timeframe would the public be informed? • One participant thought that as a mother she had a right to decide what happened if her child died. This point was made against presumed consent. • One participant pointed out that Māori health statistics and ethnic compatibility issues meant that Māori must be prepared to donate to each other. He asked if Māori were prepared to increase their rate of organ donation, and if so, how would this be achieved. • Some support was given for a proactive ad campaign, which recognised organs as taonga, to increase the rate of organ donation among Māori and others who are not well informed about this subject. • The consensus was that Māori must have a discussion with themselves in order to determine the best option for them. • Organs were seen as taonga, treasures, and there was considerable discussion around what this might mean in terms of donation. Traditionally, organ donation is a taboo subject. • Need to tell the success stories as well as highlight the concerns with organ donation.
35.	If you think one of the options (other than status quo) would be better for New Zealand, do you think there should be any time when families/whānau should be able to override the wishes of the deceased person? Why or why not? If not, do you have suggestions for managing a situation when the wishes of the deceased person are not the same as those of the family/whānau? (see pages 61-69)
	<ul style="list-style-type: none"> • Whānau should be part of the consent process and co-sign forms. Consent is about making an individual choice with collective backing, with the support of the whānau. • It's not about whānau overriding your decision, but about assuring them that your decision is right for you. • Who has the final say in separated or de facto families? Or with people with special needs?
41.	As well as informed consent, one particular safeguard that needs to be in place is a separation between the health professionals that assess a non-heartbeating donor and those that are involved in transplantation processes. Please describe any other safeguards you think should be considered. (see pages 71-72)
	<ul style="list-style-type: none"> • An advocacy service to ensure that consent issues are fully explained and the response fully understood by medical professionals.
42.	Should the new legislative framework make it clear that donation of organs or tissue from people who have died should only be on the basis that the organs or tissue are an 'unconditional gift'? (see pages 72-73)
	<ul style="list-style-type: none"> • There was support for this view, as organ donation reminds us of shared humanity and bonds to each other.
43.	Do you think that, if both parties wish to, donor families and recipients should be able to meet? If so, what type of support should be offered for this to

	happen? (see pages 72-73)
	<ul style="list-style-type: none"> • Some participants thought that the gap between donors and receivers should be closed, and that anonymity prevents closure. Donors need to be able to say goodbye and receivers need to be able to welcome an organ. It was claimed that rejection rates decrease when organs are given and received with love. • There should be provision for blessing and lifting of tapu with the consent of the families involved. Cultural needs must be met in order to show respect for tissue. • People have a right to know. • Concern was expressed at staying in a 'Victorian mode of secrecy'. Why not celebrate donated body parts? Hold birthdays? Openness is very important even if lifestyle of recipient is distasteful to donor family. • It is an honour to give and receive an organ. Where families are unhappy with recipients, it should be recognised that our common humanity is the greatest equaliser. • It was pointed out that it took us 40 years to open adoption up. It is 'the ultimate in paternalism' to decide that donor and recipient families cannot know about each other. Donor and recipient quilts in the US illustrate that each side is desperate to know about the other. • New Zealand's small population size impacts on the ability to keep donor and recipient identity anonymous. • A personal account was given of receiving an organ believed to be from an acquaintance who would not have approved of him as a recipient. • Those who do not wish to know about who the organ has come from / gone to should be able to opt not to receive information about them.
46.	Do you think tissue banking services should be regulated under the Health and Disability Services (Safety) Act, noting that this would mean the development of a national standard for tissue banking that was then audited and providers being certified accordingly? Please explain why you agree or disagree. (see pages 75-77)
	<ul style="list-style-type: none"> • Questions were asked about a possible central register of tissue held in New Zealand. How would individuals access information about held tissue?
54.	Your comments are sought on the proposed regulatory approach to tissue-based therapeutic products and any concerns you have about how it may impact on the practice of health care. (see pages 87-88)
	<ul style="list-style-type: none"> • For some Māori, tissue, organs and body parts are different things. For some they are indistinguishable.

PART D: COMMON CONCERNS FOR ALL USES OF TISSUE

55.	<p>Do you think the definition of ‘immediate family’ given below is suitable for new legislation for both the therapeutic and non-therapeutic uses of human tissue? Please explain any changes you think should be made. (Please note that this definition is not proposed for use in the risk framework for tissue-based therapeutic products described in section C5.2.6. It is only proposed for times when consent is needed.) The proposed definition is:</p> <p>a) any person who was the spouse of the deceased including de facto and same-sex partners, or a parent, grandparent, child, brother or sister, or guardian or ward, of the deceased; and</p> <p>b) any person whose relationship to the deceased is that of step-child, step-parent, step-brother or step-sister; and</p> <p>c) any person who, in accordance with the traditions and customs of the community or whānau of which the deceased is a member, had the responsibility for, or an interest in, the welfare of the deceased. (see pages 89-90)</p>
	<ul style="list-style-type: none"> • Each whānau will have its own definition.
61.	<p>Do you think the new legislation should prohibit the sale and purchase of all human tissue in New Zealand? (see pages 94-97)</p>
	<ul style="list-style-type: none"> • This was not supported.
62.	<p>If you think some sale and purchase of human tissue should be allowed, please explain what types of tissue this should apply to, for what purpose it should be allowed to be bought or sold, and who should be permitted to sell it. (see pages 94-97)</p>
	<ul style="list-style-type: none"> • Protection over sale of tissue: who covers health and safety issues?

OTHER ISSUES RAISED

- One participant told of collecting her son’s heart from Greenlane Hospital. The experience was a profoundly spiritual one. Staff at the hospital told her that everyone in her position had felt the same way.
- The ‘Western model’ of medical science, in which ‘we are but machines’, was seen as flawed. Educating Māori communities about the issues around organ donation should take into account understandings of Māori ancestry, spirituality, connection to the earth, and lack of fear about death. We need to recognise when our time has come and not be afraid about it. Māori must not be approached with the attitude that if they only knew, they would agree.
- Western medicine sees informed consent as a matter of personal consent. We need to challenge this paradigm.
- Māuri (life force) travels with organs and has been detected in terms of cellular memory.

- Many Māori health practitioners are in two minds about organ donation. From a medical perspective, they want to save lives, but they want to do so in ways that are acceptable to the Māori community.
- The significance to Christians of someone giving their life for you (by donating their organs) was discussed by some participants.
- If laws do not recognise Māori views, they may go back to the old ways and refuse to abide by laws determining what is to happen to the dead and where they were to be buried.