

REVIEW OF THE REGULATION OF HUMAN TISSUE AND TISSUE-BASED THERAPIES: PAPER ONE: OVERVIEW AND PRINCIPLES FOR HUMAN TISSUE LEGISLATION

Proposal

1. This paper provides the rationale for a new regulatory framework for the use of human tissue and an overview of proposals for regulating human tissue and tissue-based therapies, including the proposed scope and structure of new legislation to regulate the use of human tissue. It also seeks Cabinet agreement to include a set of overarching principles in the legislation to guide the drafting of new Human Tissue legislation.

Executive Summary

2. This is the first of a suite of three papers which seeks agreement to a new regulatory framework for human tissue and tissue-based therapies, including agreement to:
 - repeal the Human Tissue Act 1964 and replace it with new Human Tissue legislation; and
 - regulate tissue-based therapeutic products under the trans-Tasman Joint Agency.
3. At present, the regulatory framework for human tissue spans a number of acts and regulations. Individually, many of these acts and regulations are considered to be out-of-date (eg. the Human Tissue Act dates from 1964), and collectively they do not comprise a comprehensive or fully effective framework. Increasingly, issues are raised that either fall outside the scope of the current arrangements or are subject to varying interpretations.
4. The proposals to establish a new regulatory framework for human tissue have been developed on the basis of the Ministry of Health's review of the regulation of human tissue and tissue-based therapies (the 'Human Tissue Review'). The new regulatory framework will ensure appropriate management, oversight and monitoring of the collection, use, retention and disposal of human tissue for therapeutic (e.g. organ transplantation) and non-therapeutic (e.g. education, research, audit) uses of tissue.
5. The key elements of the proposed new human tissue legislation are -
 - Establishing a consent framework for the collection, use, retention and disposal of human tissue from deceased people for both therapeutic and non-therapeutic uses (addressed in Paper Two).

- Requiring a standard for the management and oversight of tissue taken for non-therapeutic purposes (from living and deceased people) such as audit, education, and research purposes (addressed in Paper Three).
 - A category of 'controlled activities' to enable the new legislation to manage any risks associated with new developments in science and research that cannot necessarily be predicted at the moment (addressed in Paper Three).
 - Revokes Part 3A of the Health Act 1956, which regulates trading in donated blood and controlled human substances, and incorporates similar provisions in new Human Tissue legislation to cover trading in all human tissue, including blood (addressed in Paper Three).
6. I am also seeking your agreement to regulate the therapeutic use of tissue through the trans-Tasman Joint Therapeutic Products Agency and regulatory scheme (addressed in Paper Three).

Background

Introduction to the Review

7. The recommendations in this Cabinet paper arise from the Human Tissue Review undertaken over 2003-2004 by the Ministry of Health. The Human Tissue Review addressed issues related to the collection, use, retention and disposal of human tissue in both the therapeutic and non-therapeutic contexts.
8. The key drivers for the Review were:
- Ongoing developments in new technology and changes to therapies. For example, xenotransplantation and stem cell technology present new ethical and safety challenges.
 - Safety issues. Tissue-based therapeutic products including organ transplants, tissue transplants and cellular therapies are currently subject to minimal formal safety requirements. The lack of formal requirements impacts on the ability to assure the safety of therapeutic products and the ability to track the use of a product should an adverse event occur.
 - Public concerns. Public concern has been expressed in a number of areas of human tissue use including, for example, organ donation, and the retention of tissue following post-mortem examinations (e.g. retention of children's hearts at the Greenlane Heart Library).
 - Ethical issues. Ethical consideration of research and innovative practice proposals is a core part of the health and disability sector. However, ethical issues have arisen, for example, in relation to the commercial use of tissue, where I consider that the legislation could provide better guidance to assist ethical decision-making.

- Consistency with work in other sectors. Currently legislation in other areas is being reviewed and this work intersects with the human tissue area. For example, a new Coroners Bill is currently before the Justice and Electoral Reform Select Committee and new legislation has recently been enacted to cover the human assisted reproduction area.

Consultation on the Human Tissue Review

9. In 2004, the Ministry of Health published a discussion document on the Human Tissue Review. This discussion document formed the basis of public consultation, which was undertaken in April - June 2004. The Ministry received 125 written submissions from a wide range of organisations and individuals. It also held a series of 10 meetings, seeking feedback on the discussion document including: meetings in Wellington, Christchurch, Dunedin and Auckland; public hui in Rotorua and Christchurch; and invitation-only focus groups with Māori (two groups), Pacific peoples, and chairs of regional ethics committees.
10. In September 2004, I agreed to the public release of the Summary of Submissions document with copies posted to submitters, the Health Select Committee, members of the media, and other interested parties. The Summary of Submissions document is also available on the Ministry's website.
11. Following the formal consultation process, my officials met with a number of individuals and organisations involved in the collection, use and retention of human tissue, consumer groups, and other government agencies to test the Ministry's proposed options on informed consent and preferred regulatory options. Officials also met with iwi representatives in Rotorua and Turangi, at their request, to provide feedback on the key issues arising from the public consultation process.
12. Feedback from the formal consultation process and subsequent meetings with the sector and consumer groups is reflected in the discussion on the various policy proposals in the three Cabinet papers.

Proposals for Change

13. The objectives of the proposed new regulatory framework for human tissue are:
 - to appropriately promote the cultural and spiritual needs of New Zealanders and the public good associated with the use of human tissue for therapeutic and non-therapeutic purposes
 - to address the safety of tissue for therapeutic and non-therapeutic use
 - to be flexible enough to respond to advances in technology that cannot be predicted at this stage
 - to streamline, as far as practicable, the legislation relating to human tissue

- to put in place a framework that is comprehensive and easily understood by New Zealanders.

Scope and Structure of the Regulatory Framework

14. I propose a new regulatory framework to ensure appropriate management, oversight and monitoring of the collection, use, retention and disposal of human tissue. The policy proposals have been informed by feedback from the public consultation process, evidence from the literature, international experience (particularly the UK where new Human Tissue legislation was enacted in 2004), cost/benefit implications, legal implications, feasibility of implementation and other policy/regulatory developments. I recommend that some aspects of human tissue regulation be addressed through new human tissue legislation and other aspects be dealt with through other regulatory mechanisms. The proposed structure is summarised below, with detail around the various policy proposals provided in Paper Two and Paper Three.

<p>New Human Tissue Act – proposed structure</p> <ul style="list-style-type: none"> • Principles • Definition of tissue • Consent framework for the collection, use, retention and disposal of human tissue from deceased people for both therapeutic and non-therapeutic uses. (The Code of Health and Disability Services Consumers' Rights 1996 covers consent for tissue taken from living people) • Non-therapeutic tissue management and monitoring requirements for human tissue (taken from living and deceased people) • Controlled activities – controlling new activities that present potential safety or ethical risks (eg. xenotransplantation) • Restrictions on trading in all human tissue similar to Part 3A of the Health Act 1956 (to be repealed). • Enforcement/offences • Regulation-making powers
<p>Regulation of tissue use outside the new Human Tissue Act</p> <ul style="list-style-type: none"> • Management, oversight and monitoring of therapeutic use of tissue and blood (taken from living and deceased people) to be regulated through the trans-Tasman Joint Agency.

Principles/values underpinning new Human Tissue legislation

15. I am proposing the legislation be drafted in accordance with key principles which guide those involved in the collection, use and retention/disposal of human tissue and the development of any standards made under the legislation. The following key themes have been drawn from written submissions and consultation meetings and it is recommended that these form the basis of a set of overarching principles shaping the legislation:

(a) ***Respect for tissue and tissue donors***

Many submitters expressed the belief that tissue should be treated with respect and some considered that this should be the overarching principle for the legislation.

(b) ***Informed consent***

Informed consent¹ and individual autonomy² were central themes in consultation and overall there was strong support for informed consent as the foremost principle in the new legislative framework. Many submitters felt that people, alive or deceased, had a right to decide about the use of tissue (whether to donate or not) from the perspective of individual autonomy and many were strongly opposed to involvement by others or any modification to informed consent requirements. Many other submitters, however, acknowledged the dilemma in practice of an individual's wishes in relation to organ and tissue donation always taking priority and, across both therapeutic and non-therapeutic uses of tissue, sought compromise positions that allowed for case-by-case management of situations as they arose. For example, comment was made that while in theory it was preferable to follow the wishes of the deceased, if known, in practice this was difficult if the family was strongly opposed.

This was an important issue for Māori and for Pacific peoples who participated in the consultation process. They generally felt that informed consent must be gained for any use of tissue but that recognition of both individuals and family/whānau preferences was needed in the consent process.

There are different technical consequences depending on which principle/value is given most weight in new legislation. These consequences are presented in detail in Paper Two, which provides options for who can give consent to tissue/organ donation and the mechanism for recording that consent.

(c) ***Respect for families/whānau and for differences in culture and values***

The need for respect for families, whānau and individual cultural beliefs came through in many submissions, particularly from Māori and Pacific peoples and those who support families participating in decisions about the donation of tissue from a deceased person. From a cultural perspective it was noted that an individual is difficult to separate from their family or whānau. From a clinical perspective the need to care for grieving families at the time of organ donation was also highlighted.

¹ "A person's voluntary agreement, based on adequate knowledge and understanding of relevant information...". *Operational Standard for Ethics Committees, Ministry of Health, March 2002, p132*

² "The personal capacity to consider alternatives, make choices and act without undue influence or interference of others." *Operational Standard for Ethics Committees, Ministry of Health, March 2002, p131.*

- (d) ***Value of tissue for treatment, research and education***
Across many submissions the valuable uses of tissue for treatment, research and education were highlighted and caution was expressed about putting requirements in place that were barriers to the use of tissue.
- (e) ***Consistency across different types and uses of tissue.***
The need for as much consistency as possible across the different uses and types of tissue came through frequently in submissions. The reasons given were because of the similarity in the processes needed, similar ethical considerations, the difficulty in separating activities or types of tissue, a desire to have streamlined systems that are easily understood by the public and sector, and similarity in safety considerations across different types of tissue for therapeutic purposes and blood.

Definition of Tissue

16. I am proposing that the definitions of human tissue include whole bodies and body parts through to blood, cell lines derived from tissue, stillborn children, and foetal material.
17. The framework will exclude material covered under the Human Assisted Reproductive Technology Act.
18. It will also exclude bodily substances that are excreted or shed by the body naturally, such as hair and urine.

Consultation

19. Details of the public consultation process undertaken by the Ministry of Health are provided in Paper One of this suite of three papers.
20. The following government agencies have been consulted on this paper: Ministry of Justice; Ministry of Research Science and Technology; Ministry of Transport; Land Transport New Zealand, Police, Te Puni Kokiri; Ministry of Pacific Island Affairs; Treasury; New Zealand Customs; Ministry of Social Development, Ministry of Culture and Heritage; New Zealand Defence Force, Office of Disability Issues, Ministry of Women's Affairs; Ministry of Consumer Affairs, Department of Prime Minister and Cabinet, Health and Disability Commissioner; Office of the Privacy Commissioner.

Financial Implications

21. There are no financial implications associated with the proposals in this paper. Papers Two and Three of the suite of papers set out the financial implications associated with the proposed new regulatory framework for human tissue.

Regulatory Impact Statement

22. Based on the information provided in the attached RIS/BCCS, the Regulatory Impact Analysis Unit considers that the disclosure of information is adequate, and the level of analysis is appropriate given the likely impacts of the proposal.
23. The BCCS identifies research institutions and funeral homes as the businesses likely to incur business compliance costs. The main business compliance costs are likely to be the administrative costs of meeting the requirements in new legislation. Some institutions may need to improve their record keeping systems in order to meet the requirements for formally recorded consent. They may also need to undertake some staff training around the new requirements. The Ministry of Health will provide guidance on the implementation and interpretation of the legislation, and in particular, guidance on what is expected in terms of the information to be provided about organ/tissue donation before consent can be recognised as informed consent. This may include providing model examples of consent forms.

Legislative Implications

24. This paper proposes that the Human Tissue Act 1964 be repealed and replaced with new legislation. Legislative change is necessary because increasingly issues are raised that either fall outside the scope of the current legislation or are subject to legal interpretation.

Human Rights/Bill Of Rights

25. There are no specific Human Rights Act or Bill of Rights Act implications associated with these proposals.

Gender Equity

26. There are no specific gender equity issues associated with these proposals.

Disability Perspective

27. The New Zealand Disability Strategy requires that the perspectives of disabled people be included in ethical and bioethical debates (Action 1.4). Under the proposed Controlled Activities provisions (refer Paper Three) the Minister of Health must take into account ethical, cultural and spiritual implications before approving particular applications that fall within the list of Controlled Activities or recommending to the Governor-General that an activity be added or removed from the list of controlled activities. Before making a decision or recommendation the Minister may seek advice from either a committee she has established for that purpose or an existing body or committee. Any such body would be required to consult with interested parties and members of the public before tendering advice to the Minister of Health.

Publicity

28. I recommend that the suite of Cabinet papers relating to a new regulatory framework for human tissue and tissue-based therapies and the Regulatory Impact Statement/Business Compliance Cost Statement be published on the Ministry of Health website. I also recommend that a copy of each of the three papers is forwarded to the Health Select Committee.

Recommendations

29. It is recommended that you:
 1. **Note** that this is the first in a suite of three papers seeking your agreement to a new regulatory framework for tissue and tissue-based therapies.
 2. **Note** that the proposals contained in the three papers will require the repeal of the Human Tissue Act 1964 and the drafting of a new Human Tissue Bill.
 3. **Note** that the policy proposals in this paper have been developed following an extensive public consultation process, further discussions with those involved in the human tissue sector and additional hui.

New Human Tissue Legislation

Principles

4. **Agree** that the legislation include a set of principles drawn from the key themes that emerged from the public consultation process:
 - Respect for tissue and tissue donors
 - Informed consent
 - Respect for families/whānau and for differences in culture and values
 - Value of tissue for treatment, research and education
 - Consistency across different types and uses of tissue.

Definition of tissue

5. **Agree** that, for the purposes of the legislation, human tissue be broadly defined to include whole bodies through to blood, cell lines derived from tissue, stillborn foetuses, aborted foetuses and foetal material.
6. **Agree** that it will exclude material covered under the Human Assisted Reproductive Technology Act 2004 and bodily substances that are excreted or shed by the body naturally (e.g. hair, urine).

Financial Implications

7. **Note** that Papers Two and Three of the suite of papers set out the financial implications associated with the proposed new regulatory framework for human tissue.

Legislative implications

8. **Agree** to repeal the Human Tissue Act 1964 and replace it with new legislation.
9. **Note** that Papers Two and Three of the suite of papers seeking agreement to a new regulatory framework for human tissue contain the detailed policy proposals and associated legislative implications.
10. **Agree** that the legislative changes will be binding on the Crown.
11. **Invite** the Minister of Health (Hon Annette King) to issue drafting instructions to Parliamentary Counsel Office to give effect to Cabinet's decisions on those of the above recommendations to be effected through the new Human Tissue Act.
12. **Note** that the Human Tissue Bill has priority four on the Government's legislative programme.

Publicity

13. **Agree** that this paper along with the other two papers in the suite of papers relating to a new regulatory framework for human tissue and tissue-based therapies be publicly released on the Ministry of Health's website.

Annette King
Minister of Health