



TSANZ

The Transplantation Society of Australia and New Zealand

TSANZ Board members – Professor Wai Lim and Professor Kate Wyburn

National legislative framework

Proposal 1: We welcome the goal to maintain national consistency of human tissue laws across states and territories.

Proposal 2: We agree to this proposal

Proposal 3: Comments

1. The Organ and Tissue Authority (OTA) should still oversee organ donation/retrieval process and policies relating to the use of donor tissues/cells for research (but not deciding how or what research projects are to be conducted – just the policy surrounding the storage/use of donor-derived tissues/cells at a national level). A minimum national standard for retrieval process/accreditation should be established, plus the promotion of public education, avoiding separate state/territory-based approval process/policies. The Transplantation Society of Australia and New Zealand (TSANZ) should be a stakeholder in this process.
2. Transplantation/Human Leukocyte Antigens (HLA) typing – we view OTA as the “enabler” to ensure the success of these programs, but TSANZ should provide oversight (with funding) to create new statutory regulatory bodies for transplantation and immunogenetics given it already has established interest groups and a track record in policies and guideline development, data collection, and liaising with state transplant advisory committees (TAC), as a joint approach.

For oversight of outcomes, the statutory regulatory bodies should work with the state’s TAC to arrange external auditing process for transparency. The minimum standard of outcome will need to be decided and agreed by each state’s TAC, but what constitute an outlier and management of outliers will need to be thought through – not to “punish” outliers but to enable improvements by identifying potential deficiencies to enhance program.

3. Processes, OTA for donation/retrieval and TSANZ statutory regulatory bodies for transplantation/immunogenetics, to fast-track critical projects that may inform policies, including enabling an expedited process of extracting data and linkage to the National Blood Authority (NBA) or other national data repository etc.
4. Gene technology will need separate regulations.
5. Pharmaceutical and technology bodies to fast-track novel technology and medications that may assist improvement in the donation and transplant fields.
6. Specific National Health and Medical Research Council (NHMRC) and the Medical Research Future Fund (MRFF), targeting translational donor and transplant research.



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Human tissue:

7. The terminology of cells, solid organs and non-solid organ tissues should be separated for the purpose of transplantation (organ transplant defined as transplants that would require anti-rejection drugs). The governance, use and research are quite different.
 - Regulator for cells is quite separate and different than expertise as above.
 - Faecal and foetal tissues or blood products etc. should be separated from above.
8. Discussion re: death definition seems convoluted but largely supportive of Normothermic Regional Perfusion (NRP). The Intensive Care Unit (ICU) definition seems most sensible and in accordance with international guidelines. The concern regarding public perception suggests the need to prioritise (and perhaps the first step in 2026) early engagement with the public but a clear “death” definition will need to be presented to the public.

How this can be achieved at a national level is unclear. Should this form part of donor consent (to allow use of other interventions/pre-mortem interventions + potential NRP for the purpose of donation)?

9. It is unclear how proposal 22 will work in real life scenarios.

What is the committee and how can this be standardised?

Queries regarding statements in the discussion paper

Page 18: Increasing access to human tissue and its benefits

2.11 There is a shortage of organs for transplantation in Australia. Statistics suggest that: at any one time there are 1,850 people on the transplant waiting list. But this is only the tip of the iceberg – there are 13,000 people on dialysis who could benefit from a transplant.

Comment: While there are 13,000 people on dialysis, we don't think that there are 13,000 people who would benefit from transplantation.

Page 23: Promoting Equity

Question 3 and 4



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Comment: We do not think that there is anything additional to include in new human tissue legislation to promote equity, other than proposal 25 (addressing next of kin) and proposal 46 and 48 (re disclosure of information of deceased donors by their families).

Page 24: Human tissue policy is designed to promote equitable access

3.4 The TSANZ is the body responsible for developing, on OTA's behalf, eligibility criteria for organ transplantation, and allocation protocols for organs from deceased donors.

Comment: TSANZ does not develop eligibility criteria on OTA's behalf, OTA provides TSANZ with funding to maintain current, nationally uniform eligibility criteria and allocation protocols.

Page 29: Definition of human 'tissue

Comment: We agree with proposal 7 and 8m, noting "the definition of tissue" is complex.

Page 40: New statutory provisions for determining death

Comment: We agree with proposal 10 and 11. Legislation could either sit under a uniform death act or each state and territory to have an intergovernmental agreement and that there be a consistent approach to future amendments to these provisions.

Page 41: The Dead Donor Rule

Comment: For proposal 13 (3) "Where the deceased person's respiration is not being maintained by artificial means", we would like to state that a DCD donor does not need formal brain death testing.

Page 54: Point 5.66 and 5.67: Allowing for NRP to develop in Australia

Comment: We welcome the acknowledgement of the potential benefit of NRP, and that Australia falls behind international standards in organ donation and transplantation as a result of barriers to NRP.



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We welcome the statement that ‘NRP should not be legally prohibited despite the continued ethical concerns’.