
Medical law reporter

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NEW AUSTRALIAN FEDERAL ORGAN AND TISSUE DONATION LEGISLATION: ENHANCED TRANSPLANT SERVICES BUT NO “OPT-OUT”

Seriously ill people who could achieve many years of high-quality life with organ donation continue to die on waiting lists due to the scarcity of donated organs. Recent advances that suggest donor organs can be coated with host stem cells to reduce or remove the need for long-term recipient immuno-suppressive medication highlight the importance of encouraging such donation. A wide variation in organ donor rates in developed nations suggests this is one issue in which the right regulation can make a difference. Australia has now passed federal legislation on the topic. This column considers whether that legislation is headed in the right direction.

INTRODUCTION

Synthetic biology utilising nanotechnology-sculpted organs may one day be able to replace malfunctioning hearts, livers, kidneys and other organ systems much as metal implants can now be inserted to take on the functions of hip or knee joints. The prospect of growing non-immune rejecting replacement organs from patients' own stem cells is a more imminent one, but on best predictions will still take several decades to realise as a reliable clinical treatment for organ failure. In the meantime, seriously ill people who could achieve many years of high-quality life with organ donation, continue to die on waiting lists due to the scarcity of donated organs. Recent advances that suggest donor organs can be coated with host stem cells to reduce or remove the need for long-term recipient immuno-suppressive medication highlight the importance of encouraging such donation.¹ A wide variation in organ donor rates in developed nations suggests this is one issue in which the right regulation can make a difference.

The passage of the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) (the Act) in the last sitting month of the Australian Parliament for 2008 represents another major attempt to increase the number of organ donations which take place in Australia. This column examines the intended effect and scope of the legislation and highlights some systemic problems which still remain unaddressed. Broader medico-legal issues relating to organ donation have been well canvassed in many places and will only be examined insofar as the new Act directly addresses them.²

BACKGROUND TO THE LEGISLATION

Despite reported widespread community support and a series of official promotional campaigns, organ donation rates in Australia are significantly lower than in many other comparable nations in the Organisation for Economic Cooperation and Development (OECD).³ Organ donation and transplanta-

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¹ A team recently removed cells and MHC antigens from a human donor trachea, which was then readily colonised by epithelial cells and mesenchymal stem-cell-derived chondrocytes that had been cultured from cells taken from the recipient (a 30-year-old woman with end-stage bronchomalacia). This graft was then used to replace the recipient's left main bronchus. See Macchiarini P et al, "Clinical Transplantation of a Tissue-engineered Airway" (2008) 372 (9655) *Lancet* 2023.

² For example, Kerridge IH, Saul P, Lowe M, McPhee J and Williams D, "Death, Dying and Donation: Organ Transplantation and the Diagnosis of Death" (2002) 28 *Journal of Medical Ethics* 89; West R and Burr G, "Why Families Deny Consent to Organ Donation" (2002) 15(1) *Australian Critical Care* 27.

³ Thomas M and Spooner D, *Australian Organ and Tissue Donation and Transplantation Authority Bill 2008* (Bills Digest) No 59, 2008-2009 (13 November 2008) p 3.

tion are considered acceptable – indeed, noble – by the general community.⁴ However, the low levels of *actual* donation, as opposed to registered *intentions* to donate, suggest either that families say one thing to pollsters and another to their beloved's treating physician, or that institutional problems exist which operate to diminish or override the intentions of donors. These problems could include lack of sufficient transplant specialists and teams as well as supporting hospital facilities.

Approximately 1,800 Australians are awaiting an organ donation, with almost 100 dying each year because a suitable replacement organ cannot be located.⁵ Clinically, the survival rates for transplantees in Australia are encouraging, with over 90% of organ donees surviving for more than one year and 30,000 Australians are alive today because of donated organs and tissue.⁶

For those on the donation waiting lists, however, the news is less positive. An absence of specific constitutional power to the Federal Government means that Australia's legislative approach to organ donation has, essentially, been managed on a State and Territory basis. Indeed, as noted in the Act's Digest, each hospital within a State may have its own policy dealing with organ donation.⁷ Along with a prohibition on the sale of human organs and tissue, all Australian jurisdictions have adopted various methods of "opting-in" to becoming a donor. The most common method involves recording an intention to donate on a person's driving licence and then assisting the capacity of doctors to rely on that (after consultations with relatives) to broach the issue of organ donation once the diagnosis of brain death has occurred or is imminent.⁸

In 2005, following discussions with State and Territory Health Ministers, the Federal Government created the Australian Organ Donor Register as the "only national register" of donor intention.⁹ Yet, while Medicare Australia's register has over 1.1 million registered donors, only 10 Australians per million will have their organs removed after their death.¹⁰ This compares poorly to many European nations including Spain which, with 34.3 donors per million, has the highest donation rate in the world.¹¹ Such a difference strongly suggests that this is one area of health policy where the right legislation can play an important role in clinical outcomes.

SCOPE OF THE LEGISLATION

In contrast with the multifarious and often prolix State and Territory Human Tissue and Transplantation Acts, the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth) is an Act marked by its brevity. The Act came into effect on 1 January 2009.¹² From the start of 2009 a new Commonwealth agency – the Australian Organ and Tissue Donation and Transplantation Authority (the Authority) – came into existence. It is headed by a Chief Executive Officer (CEO), whose official tasks according to s 11(1) of the Act specifically include the following:

- (a) to formulate, in writing, policies and protocols relating to organ or tissue donation and transplantation matters; and
- (b) to declare, in writing, standards and codes of practice relating to organ or tissue donation and transplantation matters; and

⁴ Commonwealth of Australia, Senate, *Debates* (13 November 2008) p 11 (proof) (Senator Ludwig).

⁵ Commonwealth of Australia, Senate, *Debates* (13 November 2008) p 11 (proof) (Senator Ludwig); Commonwealth of Australia, Senate, *Debates* (13 November 2008) p 38 (proof) (Senator Sterle).

⁶ Commonwealth of Australia, Senate, *Debates* (13 November 2008) p 11 (proof) (Senator Ludwig); Commonwealth of Australia, Senate, *Debates* (13 November 2008) p 36 (proof) (Senator Carol Brown).

⁷ Thomas and Spooner, n 3, p 4.

⁸ See eg *Human Tissue Transplant Act 1985* (NT); *Human Tissue and Transplant Act 1982* (WA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Transplantation and Anatomy Act 1978* (ACT).

⁹ Medicare Australia, *Organ Donor Register* (November 2008), <http://www.medicareaustralia.gov.au/public/services/aodr/index.jsp> viewed 25 November 2008.

¹⁰ Thomas and Spooner, n 3, p 3.

¹¹ Thomas and Spooner, n 3, p 5. Compare also, "Belgium has a rate of 28 donors per million people and Austria has 23.6 donors per million people": Commonwealth of Australia, Senate, *Debates* (13 November 2008) p 35 (proof) (Senator Humphries).

¹² *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth), s 2.

- (c) to support and encourage the implementation of:
 - (i) policies and protocols formulated under paragraph (a); and
 - (ii) standards and codes of practice declared under paragraph (b); and
- (d) to collect, analyse, interpret and disseminate information relating to organ or tissue donation and transplantation matters; and
- (e) to support, encourage, conduct and evaluate training programs that are directed towards improving the skills and knowledge of people involved in organ or tissue donation and transplantation services; and
- (f) to support, encourage, conduct and evaluate educational, promotional and community awareness programs that are relevant to organ or tissue donation and transplantation matters; and
- (g) to make, on behalf of the Commonwealth, grants of financial assistance in relation to organ or tissue donation and transplantation matters; and
- (h) to support, encourage, conduct and evaluate research about organ or tissue donation and transplantation matters; and
- (i) to publish (whether on the Internet or otherwise) reports and papers relating to organ or tissue donation and transplantation matters; and
- (j) to advise the Minister about organ or tissue donation and transplantation matters; and
- (k) to consult and co-operate with other persons, organisations and governments on organ or tissue donation and transplantation matters; ...

Throughout the Act the phrase “organ or tissue donation and transplantation matter” is used to define the jurisdiction of the Authority and the CEO. It is defined in s 4 of the Act as:

a matter relating to organ or tissue donation and transplantation, and includes the following matters:

- (a) the provision of an organ or tissue donation and transplantation service;
- (b) the identification of potential organ or tissue donors;
- (c) the obtaining of organs or tissue for transplantation;
- (d) waiting lists for potential organ or tissue recipients;
- (e) the allocation of organs or tissue for transplantation;
- (f) support services for organ or tissue donors and their partners and families;
- (g) the skills and knowledge of people involved in providing organ or tissue donation and transplantation services;
- (h) public knowledge about, and confidence in, organ or tissue donation and transplantation services.

As is made clear from the Act’s title, the Authority’s ambit extends to both tissue and organ matters, with the former described as:

- (a) a part of a human body (other than an organ); or
- (b) a part of an organ; or
- (c) a substance extracted from, or from a part of:
 - (i) an organ; or
 - (ii) any other part of a human body;

but does not include a substance or thing specified in the regulations.¹³

Presently, no excluded tissues (under s 4) are prescribed by regulations. This would mean that controversial tissues such as human ova and sperm would constitute tissues for the purpose of the Act. With the post-mortem extraction, storage and later implantation of these tissues raising difficult political and legal questions – recently in Victoria – it remains to be seen whether these tissue types will remain within the scope of the Authority.¹⁴ It should, however, be noted that the Act is explicitly designed not to override State and Territory legislation, but to complement local laws.¹⁵

In performing her or his functions, the CEO is to be assisted and advised by the Australian Organ and Tissue Donation and Transplantation Advisory Council (the Advisory Council), which is to consist of “a Chair; [and] at least 9, and not more than 15, other members”.¹⁶ Members of the Advisory Council are appointed by the federal Health Minister following consultation with the relevant

¹³ *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth), s 4.

¹⁴ *Y v Austin Health* [2005] VSC 427.

¹⁵ *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth), s 59.

¹⁶ *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth), ss 31, 33.

Ministers in each State and Territory but while the requirement for consultation is mandatory, there is no legislative bar to the federal Minister appointing preferred candidates over the wishes of the States. Members of the Advisory Council serve part-time and are required to have

substantial experience or knowledge in at least one of the following fields:

- (a) public administration;
- (b) an organ or tissue donation and transplantation matter;
- (c) business;
- (d) management;
- (e) finance;
- (f) health consumer issues;
- (g) any other appropriate field of expertise.¹⁷

No details have been forthcoming at the time of writing as to who will be appointed as CEO or who will be appointed to the Advisory Council.

If one is trying to discern what is different about the approach of this legislation, the most probable insight is that while increased national coordination and promotion of organ public awareness donation campaigns and institutional policies will take place, the new Authority has power to divert funds towards hospitals willing to develop the staffing and facilities required for “fast-track” organ transplant systems. The intention thus appears to be to create a “pull” mechanism, a type of “build-it-and-they will come” approach. Once the public knows that a major hospital in its area offers a state-of-the-art organ transplant system with excess capacity for operations, they will be encouraged to signify their willingness to donate. This analysis appears to be borne out by an examination of funding for the Authority.

FUNDING FOR THE AUTHORITY

At the 2008 Council of Australian Governments (COAG) the Commonwealth agreed to appropriate \$151.1 million over four years to fund the Authority.¹⁸ Key features of the funding include:

- \$67 million over four years to fund dedicated organ donation specialist doctors and other staff in public and private hospitals;
- \$17 million over four years in new funding for hospitals to meet the additional staffing, bed and infrastructure costs associated with organ donation;
- \$13.4 million over four years to continue national public awareness and education;
- \$1.9 million over four years for support for families of deceased donors; and
- other significant measures including enhanced professional education programs, consistent clinical protocols, “clinical trigger” checklists to help hospital staff to appropriately identify potential donors and data collection for organ transplants in hospitals.¹⁹

It is thus clear that well over half the funding of the new Authority is dedicated to enhancing the medical facilities necessary to perform organ transplant surgery.

CONCLUSION

In debating the legislation in the Senate, Senator Humphries (Liberal, ACT) stated that it represented a missed opportunity for this body to consider important alternatives to the current donation regime in Australia. Spain has the highest donation rate in the world, namely 34.3 donors per million people. Belgium has a rate of 28 donors per million people and Austria has 23.6 donors per million people. Australia’s rate of 9 per million people falls far behind these countries.²⁰

At present in Europe (where the issue is being debated in term of revision of the European *Bioethics Convention*) over 20 nations have an “opt-out” system for organ donation. The upshot is that when people are issued with a driver’s licence they are listed as a potential organ donor unless they

¹⁷ *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* (Cth), s 34.

¹⁸ *Australian Organ and Tissue Donation and Transplantation Authority, Explanatory Memorandum* (2008) p 1; Thomas and Spooner, n 3, p 8.

¹⁹ *Australian Organ and Tissue Donation and Transplantation Authority, Explanatory Memorandum* (2008) p 1.

²⁰ Commonwealth of Australia, Senate, *Debates* (13 November 2008) p 35 (proof) (Senator Humphries).

specifically request that designation to be removed. This alters the focus of the moral choice involved. Rather than having to prompt oneself to overcome, for altruistic reasons, irrational fears of provoking death by considering it, the donor under an “opt-out” system still has to confront the spectre of demise but this time in order to assert in some measure their rejection of this specific form of altruism. There is a problematic entelechy for both the spiritually minded and for atheists (and enhanced opportunities for those on the transplant list) in requiring donor refusers to ponder that potentially rather lame contribution to the state of their consciousness/soul/character on departure from this existence. If the new Authority were to work towards an “opt-out” organ donation specification on Australian drivers’ licences, that would go a long way to effectively complementing the increased funding for transplant medical services in the Act, as would initiatives by the Authority to encourage medical students to move into the world of stem-cell-enhanced organ donation.

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