

Organ and Tissue Donation and Transplantation

2017

1. Preamble

1.1 The AMA supports organ and tissue donation and strongly encourages individuals to consider their views on donation and discuss them with their family.

1.2 One organ and tissue donor can help more than 10 people by saving a life, improving the quality of life and restoring body function. Organs that can be donated include the heart, lung, kidney, liver and pancreas. Tissues that can be donated include the eyes, heart valves, skin and musculo-skeletal tissue.¹

1.3 Australia is a leader in organ and tissue transplantation in terms of transplant outcomes. While donation rates are continually improving as a result of reform measures introduced since 2009, there remains potential for further growth. In Australia, as with all developed countries, there continues to be insufficient donated organs to meet the needs of those who might benefit from transplantation.

1.4 By increasing Australia's rate of organ and tissue donation, more individuals and their families have the opportunity to benefit from receiving life-enhancing organs and tissue transplants. This has a positive impact on the healthcare system as transplantation of organs and tissues, such as kidneys and corneas, is cost-effective compared to the expense of providing ongoing treatment for those waiting for a transplant.

1.5 Public trust and confidence in the organ and tissue donation and transplantation system is critical for increasing donation rates. Individuals may be more willing to donate their organs and tissues if they trust the system to be fair, accountable, transparent and safe. This requires a robust ethical framework incorporating the following principles:²

-) Donation is altruistic, for the benefit of others;
-) The choice to donate is informed and voluntary;
-) The choice to donate (or not) is respected. This includes a right to change a donation choice;
-) The family's consent to donate (or not) their relative's organs or tissues is respected;
-) Donor families are treated with respect, compassion and dignity;
-) The needs of the donor and their family take precedence over organ procurement;
-) Organs and tissues are allocated fairly;
-) The recipient consents to transplantation;
-) The privacy and confidentiality of donors and recipients is respected;
-) The primary obligation of doctors is to patients, whether they are potential donors or recipients. It can be seen as a conflict of interest for the same medical team to look after both the potential donor and the recipient. Where practicable, there should be a separation of roles between:
 - o the medical team involved in caring for the donor and their family,
 - o the medical team involved in retrieving the organs and tissues, and
 - o the medical team involved in caring for the recipient.

However, the process of obtaining consent for organ donation must be clearly independent from decision-making regarding the care of the potential donor.

-) The system for undertaking organ and tissue donation and transplantation is safe, accountable, transparent, and has the capacity to meet the current and future demands for, and availability of, organs and tissues.

1.6 Appropriate public education and awareness is another important factor in increasing organ and tissue donation rates. Public campaigns will not only make individuals aware of the shortage of donor organs and tissues and the opportunities for donation but will also educate individuals on the facts of organ and tissue donation. Public education supports individuals in making truly informed donor decisions and enhances confidence in the system, resulting in more individuals willing to become organ and tissue donors.

1.7 Public willingness to donate organs and tissues also requires a health system that has the capacity to meet the current and future demands for, and availability of, organs and tissues. This includes not only adequate clinical staff, hospital infrastructure and communication and coordination networks but also specialist trained staff readily available to help identify potential donors and to support family members who are faced with making a donation decision, often during a highly emotional and stressful time.

1.8 The opportunity for organ donation is an infrequent event. It comes at an intensely emotional time for families and can be challenging for all involved. Health professionals who work in this area require training and specific knowledge to support families and their decision-making. Excellent care and communication ensures that families are supported during the donation process. The aim is that families make a donation decision that acknowledges the patient's wishes, if previously known, their views and preferences, and that surviving family members will be comfortable with the decision.¹

1.9 A nationally-coordinated approach to organ and tissue donation is essential to increase donation and transplantation rates. The system that oversees organ and tissue donation and transplantation should be based on accountability, transparency, safety and fairness.

1.10 In 2009, Australia's Organ and Tissue Authority (the Authority) was established under the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* ([the Act](#)). The purpose of the Authority is to develop a nationally coordinated approach to organ and tissue donation for transplantation in liaison with States and Territories, consumers, clinicians and the community.³

1.11 While it is essential that Federal, State and Territory governments commit to increasing organ donation rates in Australia, it is equally important that governments continue to promote programs that focus on preventing and treating organ failure in the first place.⁴

2. Determination of death

2.1 Organs and tissues may be donated by deceased donors or living donors.

2.2 In Australia, only 1-2 % of people who die in hospital do so in the circumstances that will enable organ donation.^{1,2} Such patients have usually experienced a sudden illness or injury necessitating the provision of life supportive treatments including mechanical ventilation in the setting of an Emergency Department or Intensive Care Unit.

2.3 Donation of organs and tissues after death is governed by laws. In 1977, the Australian Law Reform Commission addressed the absence of a definition of death in Australian law, recommending that a statutory definition of death should be introduced.⁵ They recommended that death be defined as:

- a) irreversible cessation of all function of the brain of the person; or
- b) irreversible cessation of circulation of blood in the body of the person.

2.4 This definition has been enacted in State and Territory laws that govern donation (Human Tissue Acts). The legal definitions of death allow for two potential donation pathways known as either donation after brain death or donation after circulatory death.

2.5 The circumstances for eye and tissue donation are less limited because they can be donated up to 24 hours after death, determined by circulatory criteria.

3. Free, informed donor choice

3.1 In Australia, as well as overseas, there continues to be debate regarding the benefits of 'opt in' vs 'opt out' consent systems for rates of organ donation. The current 'opt in' system, as used in Australia, requires the explicit consent of the individual, or where the individual donor wishes are not known, the

¹ Best Practice Guideline for Offering Organ and Tissue Donation in Australia <http://www.donatelife.gov.au/best-practice-guideline>

explicit consent of a legally-recognised substitute decision-maker, before donation can proceed. In an 'opt out' system, also known as presumed consent, individuals are considered to consent to organ donation unless they have registered an objection to donation.⁶

3.2 Either system of organ and tissue donation should be based on free, informed donor choice, involving the right to choose, as well as to refuse, to be an organ and tissue donor.⁷ A 'free' choice is one that is free from undue influence or coercion. An informed choice requires the decision-maker(s) to be fully informed, and to clearly understand and appreciate the following:

-) the clinical aspects of organ and tissue donation;
-) the current system and process for consenting to, or refusing to, be an organ and tissue donor. The consent (or refusal) process should be easily understood and readily accessible to everyone;
-) any other information relevant to the individual to make an informed choice.

3.3 An individual may consider donation of their organs and tissues after death (a deceased donor) and/or may consider donating organs and tissues while still alive (a living donor).

4. Public education and awareness

4.1. Public education and awareness of organ and tissue donation is an essential aspect to increasing donation rates. Relevant and culturally appropriate campaigns (available in a range of languages) raise awareness of the need for donated organs and tissues, provide information on the opportunities for donation and facilitate informed donor choice.

5. Facilitating an informed donor choice

5.1 An informed choice to become an organ and tissue donor requires information that is accurate, balanced, comprehensive and understandable. An informed choice should be free from undue influence or coercion.

5.2 Individuals may wish to discuss organ and tissue donation and transplantation with their General Practitioner, who can respond to questions and address concerns.

6. Making that choice known to others

6.1 Once an individual has made their choice regarding organ and tissue donation, their choice should be made known to others.

6.2 Individuals should register their donation decision regarding organ and tissue donation on the Australian Organ Donor Register. The Register records an individual's decision about donating organs and tissue for transplantation after death. The Register can be accessed by authorised medical personnel anywhere in Australia, 24 hours a day.⁸

6.3 Individuals should make their decision about becoming an organ and tissue donor known to their family members. In Australia, the family of every potential donor will be asked to confirm the donation decision of the deceased even if an individual is registered as an organ and tissue donor. Nine in ten families agree to donation proceeding when the deceased is a registered donor as it leaves the family in no doubt of their loved one's wishes.¹

6.4 Individuals have the right to change their donation decision at any time. It is important, however, to make family members aware of this and, where relevant, to change their decision on the Australian Organ Donor Register.

6.5 Doctors (or the wider medical team) should never pressure or coerce family members into consenting to donating their relative's organs and tissues.

6.6 The AMA strongly encourages families to support the donor wishes of their relative.

7. Donor families

7.1 Donation is not possible without the generosity of living and deceased donors and their families. They should be treated with respect and compassion at all times.

7.2 There are specialist trained staff who provide families with appropriate support and counseling before and after donation.

7.3 Donor families should not incur any financial costs in relation to donating a relative's organs or tissues.

8. Living donors⁹

8.1 There are unique ethical considerations relevant to living donors, where the donor undertakes a risk of harm for the benefit of the recipient. A living organ donor is someone who donates a kidney or partial liver to another person; usually a relative or close friend who has end stage kidney disease or liver failure. Bone tissue can also be donated by living individuals undergoing primary hip joint replacement.

8.2 Living organ donation is major surgery and is not without significant risk to the donor. This must be made explicit in the consent process.

8.3 Prospective donors are required to undergo extensive testing to ensure that they are physically and mentally able to donate. If surgery proceeds, the donor will require a significant amount of time off work to recover, with the standard recovery period being four to six weeks.

8.4 The AMA supports the following ethical principles specific to living donation:

-) Living donation must be altruistic;
-) Living donation should take place only where there are clinically acceptable risks of short and long-term harm to the donor and a high likelihood of success for the recipient;
-) Living donors must consent to donation. The decision to donate must be free and informed;
-) The living donor has the right to change their mind regarding donation;
-) The autonomy and welfare of the living donor should take precedence over the needs of the recipient to receive an organ or tissue;
-) There should be independent and separate assessment, advice and advocacy for the living donor.

8.5 Decision-making in living donation becomes particularly challenging when it involves a potential donor who lacks decision-making capacity (e.g. a child). Living donation from an individual who lacks decision-making capacity should only be considered in exceptional circumstances, where:⁹

-) the risk to the donor is clinically acceptable and the tissue is regenerative;
-) donation is a last resort and there is no other donor available;
-) donation is to a close relative;
-) the parents or guardian consents to donation. Efforts are made to ensure the potential donor understands and appreciates the significance of donation, as much as possible, relevant to their decision-making capacity;
-) an independent judgement considers the donation is not contrary to the donor's overall best interests (eg., where a child donor may save the life of their parent or sibling);
-) any additional required legal authorisation is obtained, when relevant (eg., court or tribunal).

8.6 The Supporting Living Organ Donors Program (the Program) seeks to raise the profile of living organ donation and also encourage employers to support donors.ⁱⁱ The aim of the Program is to ensure that cost is not a barrier for living organ donors to donate a kidney or part of their liver by providing a financial contribution to employers to either replenish an employee's leave or contribute

ⁱⁱ <http://www.health.gov.au/internet/main/publishing.nsf/content/leave-for-living-organ-donors>

towards reimbursing an employer who has made a payment to their employee in place of income lost due to organ donation.

8.7 Umbilical cord blood banksⁱⁱⁱ

8.7.1 Following their baby's birth, some parents may wish to donate the umbilical cord blood to a public cord blood bank, where it is made available for use by anyone in need of a blood stem cell transplant, or pay a commercial service to store the cord blood in a private cord blood bank, where it will only be available for the baby's future use.^{iv}

8.7.2 While cord blood can be used in the treatment of a range of blood disorders and conditions of the immune system, there is currently insufficient evidence that cord blood can prevent or cure a wide range of diseases (as claimed by some commercial services).¹⁰

8.7.3 When considering whether to store cord blood in a public or private facility, parents should be fully informed of the best available, objective evidence for current and future uses of cord blood in the prevention and treatment of disease.

9. Transplant waiting lists

9.1 Patients should be referred in a timely manner for assessment for suitability to be placed on a transplant waiting list.

9.2 In accordance with The Transplantation Society of Australia and New Zealand¹¹, patients should be regularly reviewed to determine if they remain suitable for transplantation. An individual patient's suitability for transplantation may change over time due to their changing health conditions. Such a change may move them up, down or even off the list if they no longer meet eligibility criteria, either permanently or temporarily.

9.3 It is important that patients and their referring doctor be kept informed if their status changes, the reasons for the change and the chance of being reinstated to the list (if they have been removed). A patient deemed ineligible for the waiting list, or who has been removed from the waiting list, should have the right to appeal the decision through a process of impartial review.¹²

10. Allocation of organs and tissues

10.1 There is a need to consider both equity and utility when determining eligibility to receive organs and tissues.¹¹ The process for allocating available organs for transplantation must be fair, equitable, accountable and transparent, from placement on the waiting list to distribution of organs amongst those on the list. Allocation of organs should be based on clear clinical and ethical criteria aimed at achieving the best overall outcomes for the recipient and the appropriate use of scarce resources.¹²

10.2 There should be no discrimination against potential recipients based on factors that are not medically relevant. These may include (but are not limited to):¹²

-) Social status, gender, race, cultural or religious beliefs, sexual preferences, disability or age;
-) The need for a transplant arising from the medical consequences of past lifestyle;

ⁱⁱⁱ Umbilical cord blood is the blood remaining in the umbilical cord and placenta after a baby's birth. Cord blood is rich in stem cells which can be used in the treatment of a range of blood disorders and conditions of the immune system in children and adults. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Umbilical Cord Blood Banking. <https://www.ranzcog.edu.au>.

^{iv} In a public cord blood bank, the blood is donated and made available for use by anyone in need of a blood stem cell transplant. There is no fee for processing or storing cord blood in a public cord blood bank. Private cord blood banks promote the concept of storing cord blood for a baby's own use should the child become ill in the future. Private cord blood banks are commercially operated and charge a fee for processing and storing the cord blood. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Umbilical Cord Blood Banking. <https://www.ranzcog.edu.au> and the Australian Bone Marrow Donor Registry. Cord Blood Information. <http://www.abmdr.org.au>.

-) Capacity to pay for treatment;
-) Location of residence;
-) Previous refusal of an organ for transplantation;
-) Refusal to participate in research.

10.3 It is acknowledged some behaviour and lifestyle choices may be associated with disease processes that reduce the likelihood of successful transplantation and are thus medically relevant considerations. It is appropriate to take the following factors into account:¹²

-) Relative urgency of need;
-) Medical factors which affect likelihood of success (eg., tissue matching);
-) Relative severity of illness and disability;
-) Relative length of time on the waiting list;
-) Likelihood that the proposed recipient will (be able to) comply with any restrictions and related treatment prior to transplantation;
-) Likelihood that the proposed recipient will (be able to) comply with the necessary ongoing treatment after transplantation.

10.4 The allocation of organs for re-transplantation, where the potential recipient is offered a second transplant, as well as for combined transplantation, where the potential recipient receives more than one organ at the same time (eg. heart and lung), should be based on the same criteria as for the initial transplant.¹²

11. Consent to transplantation

11.1 Potential recipients must consent to receiving a transplant. The patient should receive sufficient information in a timely manner in order to make an informed decision. Such information should include (but is not limited to):^{11,12}

-) the risks, benefit and likely outcomes of the transplantation;
-) any case-specific risks such as risks associated with organ quality or risk of disease transmission associated with a donated organ. Organs that carry an unacceptable risk for some individuals may provide benefit for others. This should be determined on a case-by-case basis by the transplant team and potential recipient;¹²
-) the risks of transplantation vs no transplantation;
-) the restrictions imposed by transplantation and related treatments.

11.2 On occasion, a potential recipient may refuse a particular transplant (e.g. a recipient refuses a transplant from a living donor). Their refusal should not jeopardise their position on the waiting list.

11.3 Some potential recipients may have limited, impaired or fluctuating decision-making capacity. Such patients should be encouraged to participate in decisions involving transplantation consistent with their level of capacity at the time a decision needs to be made. Some patients will have the capacity to make a supported decision while others will require a substitute decision-maker.

11.4 Children who are potential recipients should be supported to understand the transplantation process as appropriate to their age and maturity while older children and adolescents should be encouraged to take an active part in decision-making.¹² The capacity to consent to transplantation in adolescents should be determined on an individual basis.

11.5 Potential recipients from culturally and linguistically diverse backgrounds, and Aboriginal and Torres Strait Islander people, should receive information and support for decision-making appropriate to their cultural and linguistic background.¹²

11.6 Every transplant recipient should receive appropriate psychological and physical support throughout and following the transplantation including support to adhere to the necessary ongoing treatment and health advice following the procedure.¹²

12. Organ trafficking, transplant commercialism and transplant tourism^v

12.1 Financial incentives and other inducements to donate organs may compromise the altruistic basis for organ donation. Payment for organs or tissues has the potential to take advantage of individuals who are economically disadvantaged or otherwise vulnerable.

12.2 In accordance with the Declaration of Istanbul:⁴

-) organ trafficking, transplant commercialism and transplant tourism should be prohibited as they violate the principles of equity, justice and respect for human dignity;
-) financial considerations or material gain must not influence the application of relevant allocation rules or override the primary consideration for the health and well-being of donors and recipients.

12.3 There are significant implications for the Australian health system in providing ongoing care for overseas transplant recipients who are at risk of blood-borne diseases and other complications.

12.4 While people should be discouraged from going overseas to obtain an organ transplantation, treatment and care should never be denied to them.⁹

13. Support for health professionals involved in organ donation and transplantation

13.1 Medical staff and other health professionals involved in organ and tissue donation and transplantation should have:

-) access to appropriate education, training and supervision. This includes General Practitioners who are encouraged to discuss organ and tissue donation with their patients as well as those directly involved in donation and transplantation;
-) access to counseling and support services.

13.2 A medical practitioner may have a conscientious objection to organ and tissue donation or transplantation; however, an objection should never put the donor or recipient at risk of harm nor should it undermine the role of organ donation and transplantation.

13.3 There should be adequate preparation for all health care professionals including trainees if they will be involved in removing organs and tissues.

13.4 The donor's body should always be treated with respect.

14. Workforce and infrastructure

14.1 The system for organ and tissue donation should be ethical, comprehensive, coordinated and sustainable. There should be adequate resources, both in terms of a suitably qualified and trained workforce as well as infrastructure, to support the current and future demands for, and availability of, organs and tissues.

14.2 A suitably qualified and trained workforce includes clinical staff, donor coordinators and other relevant health care personnel.

^v The following definitions are in accordance with the *Declaration of Istanbul*:

-) Organ trafficking – the recruitment, transport, transfer or harbouring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation;
-) Transplant commercialism – A policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain;
-) Transplant tourism – travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals, transplant centres) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population.

14.3 There should be appropriate professional education and awareness for doctors, particularly General Practitioners, who are not clinically involved in organ and tissue donation and transplantation but who play an important role in raising awareness of organ and tissue donation with patients.

15. Quality and safety⁶

15.1 In accordance with the World Health Organization, the system for organ and tissue donation and transplantation should be high-quality, safe, efficacious and fair, based on transparency and accountability.⁶

15.2 It is essential for doctors to maintain the privacy of individual donors and recipients. Public access to information on the funding, organisation, execution and (short-term and long-term) outcomes of donation and transplantation activities is important to maintain public confidence and ensure the system remains high-quality, safe, effective and fair.

15.3 The system for organ and tissue donation and transplantation should ensure:

-) the privacy and confidentiality of donors and recipients;
-) long-term follow-up of living donors, deceased donor's families as well as transplant recipients, as required;
-) data collection, evaluation and monitoring of the short-term and long-term outcomes of living donors and deceased donors' families as well as transplant recipients;
-) the capacity to detect and investigate relevant adverse events or reactions.

16. Cultural sensitivities²

16.1 The perception, values and attitude of an individual towards death as well as organ and tissue donation and transplantation may be influenced by a particular religious, spiritual or cultural belief or value. A culturally-sensitive approach that respects the rights, beliefs, perceptions and cultural heritage of individuals is essential when discussing organ and tissue donation or transplantation with individuals and/or their family members.

16.2 Trained interpreters, along with culturally and linguistically appropriate material, may be required when providing information to people from culturally and linguistically diverse backgrounds.

16.3 Aboriginal Health Workers or Aboriginal Hospital Liaison Officers may be involved when communicating with Aboriginal and Torres Strait Islander peoples.

16.4 All major religions either support organ donation or accept the right of individual members to make their own decision.¹³

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¹ Australian Government. Organ and Tissue Authority. *Facts and Statistics*. DonateLife. www.donatelife.gov.au

² National Health and Medical Research Council. *Ethical Guidelines for Organ Transplantation from Deceased Donors*. 2016.

³ Australian Government. Organ and Tissue Authority. <http://www.donatelife.gov.au/organ-and-tissue-authority-ota>

⁴ *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*. Participants in the International Summit on Transplant Tourism and Organ Trafficking Convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey, April 30 May 2, 2008.

⁵ Australian Law Reform Commission. *Human Tissue Transplants (1977)*. ALRC 7.

⁶ World Health Organization. *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*. 2010.

⁷ World Medical Association. *WMA Statement on Organ and Tissue Donation*. Adopted by the 63rd WMA General Assembly, Bangkok, Thailand, October 2012.

⁸ Australian Organ Donor Register. <https://www.humanservices.gov.au/customer/services/medicare/australian-organ-donor-register>

⁹ National Health and Medical Research Council. *Organ and Tissue Donation by Living Donors. Guidelines for Ethical Practice for Health Professionals*. Australian Government 2007.

¹⁰ The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Umbilical Cord Blood Banking. <https://www.ranzcog.edu.au>

¹¹ The Transplantation Society of Australia and New Zealand. Clinical Guidelines for Organ Transplantation from Deceased Donors. Version 1.1-May 2017.

¹² National Health and Medical Research Council. *Ethical Guidelines for Organ Transplantation from Deceased Donors*. 2016.

¹³ Australian Government. Organ and Tissue Authority. Organ donation & religion. DonateLife. http://www.donatelife.gov.au/sites/default/files/Religion_facts.pdf