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Ethical guidelines for organ transplantation from deceased donors

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Frequently asked questions

For answers to the following questions ...	See ...
How do ethical principles apply to organ transplantation?	Section 2.2
How is eligibility for transplantation assessed?	Sections 1.1 and 3.2.1 Case studies 1 to 4
Is there an opportunity for review if an individual is assessed as ineligible for transplantation?	Section 3.2.1
How are decisions made about the suitability of organs for transplantation?	Section 1.2
How long do recipients wait for transplantation?	Section 1.1
Is the allocation process the same for all organs?	Section 1.4
Which factors are taken into account when considering potential recipients for a particular organ?	Sections 1.3 and 3.2.2 Case studies 5 and 6
How are individuals supported in decision-making?	Section 3.1
How are decisions made about accepting the offer of an organ for transplantation?	Sections 1.4 and 3.1 Case studies 7 to 11
Where can I find information about consent to organ transplantation?	Sections 2.2.3 and 3.1
Can an individual receive an organ from a deceased family member?	Section 3.2.2 Case studies 12 and 13
How is the privacy of donors and recipients protected?	Sections 1.5 and 2.6.6
What information about donation and transplantation practice is kept and how is this information used?	Section 1.5
How are new developments in transplantation practice assessed?	Section 3.3 Case study 15
Where can explanations of terms used in transplantation practice be found?	Explanation of key terms
Where can further information about transplantation be found?	Appendix B

Explanation of key terms

Term	Explanation
Assent	Affirmative agreement to participate. Failing to object is not considered assent.
Consent	A person or group's agreement based on adequate knowledge and understanding of relevant material.
Deceased donor	A person, declared dead by established medical criteria, from whom organs and/or tissues are recovered for the purpose of transplantation into another person (recipient). The two pathways to deceased donation are donation after brain death and donation after circulatory death.
Donation after brain death	Organ donation after death has been determined on the basis of irreversible cessation of all brain function.
Donation after circulatory death	Organ donation after death has been determined on the basis of the irreversible cessation of circulation of blood in the body of the person.
Eligibility criteria	Criteria by which the multidisciplinary team assesses individuals to determine whether they are suitable for transplantation.
Ex-vivo	In an artificial environment outside the living organism.
Ischaemic time	The time between loss of blood supply to the donor organ and its transplantation into a recipient.
Organ	Differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy (e.g. kidney, heart, lung, liver, pancreas).
Perfusion	The passage of a fluid through the vessels of a specific organ.
Recipient	A person who receives organs and/or tissues from another person (donor).
Tissue	All constituent parts of the human body formed by cells (e.g. cornea, heart valves, bone, skin).
Vascularised composite tissue allograft	Part of the body that comprises multiple tissues such as muscle, bone, nerve and skin, as a functional unit (e.g. a hand or face).

Introduction

Organ transplantation is a highly effective treatment for advanced organ failure. Australia's organ transplantation success rates are some of the highest in the world, with a 5-year survival rate of 80% for most organs.¹ In 2015, 1,241 Australians received a transplant of an organ from a deceased donor.¹ Deceased organ donation is only possible if a person dies in a hospital under certain circumstances, usually in a hospital intensive care unit or emergency department.

The need for organs from deceased donors exceeds their availability. At any time, there are around 1,500 Australians who have been assessed as eligible and are waiting for a transplant,¹ a number of whom die before receiving a transplant as their disease progresses beyond the point at which transplantation is possible.

Given the relative shortage of donor organs it is inevitable that, whatever criteria are used to make decisions about organ transplantation, there will be many people who would benefit from an organ transplant but will not be able to receive one. It is therefore essential that organ allocation and transplantation decisions and policies are ethically robust and transparent and guided by ethical principles and values. Decision-making regarding the allocation and transplantation of donated organs seeks to balance the needs of individuals who would benefit from a transplant with the need to exercise responsible stewardship of this scarce and valuable resource.

Role of the Ethical Guidelines

These Ethical Guidelines have been developed with advice from an expert advisory group (see Appendix A) to provide an overarching framework to guide ethical practice and inform decision-making by everyone involved in transplantation of organs from deceased donors. They also inform the ongoing revision of the *Clinical Guidelines for Organ Transplantation from Deceased Donors* (Clinical Guidelines), which are maintained by the Transplantation Society of Australia and New Zealand (TSANZ).² It is anticipated that the Clinical Guidelines will be regularly updated in response to changes in the clinical and scientific environment.

The ethical principles in this document are in line with community expectations that human rights and the right to access to health care are respected and protected.

These Ethical Guidelines are also consistent with the principles outlined in international documents, such as:

- World Health Organization (WHO) Guiding principles on human cell, tissue and organ transplantation,³ endorsed by the Commonwealth of Australia
- The declaration of Istanbul on organ trafficking and transplant tourism,⁴ supported by the National Health and Medical Research Council (NHMRC) and TSANZ.

Other documents also provide guidance on transplantation practice, such as:

- *clinical guidelines*, in particular those developed by TSANZ, which support specific decision-making based on clinical criteria and predicted transplantation outcomes
- *implementation guidelines*, which describe detailed procedures and protocols at the local level (e.g. concerning tissue typing to allow matching of donor organs with potential recipients)
- *information guidelines*, which will be based on these Ethical Guidelines and the Clinical Guidelines and provide information for potential recipients and their families, carers and friends (e.g. those developed by transplantation units and hospitals and by the Organ and Tissue Authority [OTA] and state and territory bodies).

Scope of the Ethical Guidelines

These Ethical Guidelines inform ethical practice in:

- assessing the eligibility of an individual for transplantation
- assessing the suitability of donor organs for transplantation
- allocating solid organs and vascularised tissue composite allografts (such as the hand or face) from deceased donors.

The Ethical Guidelines *do not* apply to:

- the process of organ donation
- transplantation of organs from living donors
- transplantation of human tissue other than solid organs and vascularised tissue composite allografts
- transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes
- medical practice more generally.

For information on these issues, readers are referred to specific guidelines (e.g. those developed by NHMRC, TSANZ, OTA, state/territory departments or professional bodies).

All activities referred to in these Ethical Guidelines must be carried out in compliance with existing law, legislation and regulatory frameworks (see Appendix B). The activities must also comply with relevant professional and accreditation standards and the maintenance of appropriate quality management systems.

Intended audience

The Ethical Guidelines are intended for use by:

- health professionals involved in the transplantation of organs from deceased donors
- potential recipients of transplanted organs, and their families, carers and friends
- the community.

Structure of the Ethical Guidelines

The Ethical Guidelines provide information on a number of levels.

- **Chapter 1** provides background information on the current system for organ transplantation in Australia.
- **Chapter 2** highlights ethical principles and values and their application in organ transplantation from deceased donors.
- **Chapter 3** provides practical guidance on discussing transplantation (Section 3.1) and ethical decision-making specific to:
 - determining eligibility for transplantation, allocating organs and supporting individual decision-making about accepting the offer of an organ (Section 3.2); and
 - innovative transplantation practices (Section 3.3).

Case studies are included in Chapter 3 to highlight the complex ethical issues involved in decision-making about transplantation and the way in which the ethical principles and guidance can assist decision-making. In some instances, the case studies illustrate how ethical issues may be resolved.

In addition, the explanation of key terms lists how specific terms are used in these Ethical Guidelines, the section on frequently asked questions allows easy navigation to specific information and the appendices provide information on the development of the Ethical Guidelines and list further relevant resources.

1 Current system for organ transplantation

The current system for organ transplantation from deceased donors aims to allocate available organs to the individuals who have the best chance of receiving the greatest benefit from the transplant, while also taking into account equity in access to transplantation and responsible allocation of donated organs. This is based on assessment of the risks and benefits specific to the individual circumstances, which are influenced by factors related to the donor, the organ and the recipient. The clinical guidelines developed by TSANZ provide guidance for health professionals involved in transplantation in determining those individuals who may be eligible for transplantation, suitability of donated organs for transplantation and how these organs are allocated.²

1.1. How is eligibility for transplantation assessed?

The scarcity of donor organs means that clear and transparent clinical criteria for determining eligibility for transplantation are required to ensure a just and equitable system for the delivery of this treatment to the Australian community.

The clinical guidelines developed by TSANZ outline specific inclusion and exclusion criteria for eligibility for transplantation of each organ, as well as general conditions that apply across the organ types.² The clinical guidelines are reviewed regularly by TSANZ, along with data on outcomes, and the criteria updated to ensure currency with evolving clinical practice and research.

The process of determining eligibility for transplantation involves:

- referral by a specialist physician of an individual, generally with end-stage organ disease, to a transplant unit
- assessment against eligibility criteria by a multidisciplinary team at the transplant unit — this takes into consideration medical history and other relevant factors (such as the ability to adhere to medical therapy) that affect transplantation outcomes.

Waiting times for transplantation vary according to organ type. Depending on the availability of an organ suitable to the individual and the urgency of the potential recipient's need for transplantation, it may be several years before the potential recipient is offered an organ.

While they are waiting for a transplant, potential recipients receive support from a multidisciplinary team who keep them and their family informed of developments and timelines. Members of this team should include those with experience and expertise relevant to the background of the potential recipient, such as people from culturally and linguistically diverse backgrounds or Aboriginal and Torres Strait Islander people.

The transplant team regularly reviews potential recipients to ensure that they remain suitable for transplantation. Individuals may be assessed as no longer eligible for organ transplantation if their condition changes, either because their organ function improves to a point that transplantation no longer offers a benefit or because their condition deteriorates to the point where they no longer meet the eligibility criteria. Should a potential recipient or their physician disagree with an assessment made by the transplanting team regarding eligibility for transplantation, processes are in place to enable provision of a second opinion.

1.2. Are all organs suitable for transplantation?

At the time of donation, organs are assessed for their suitability for transplantation. Criteria for the assessment of organs are based on donor and organ characteristics and are informed by data collected on donation and transplantation practice and outcomes (see Section 1.5). These criteria are set out in Clinical Guidelines developed by TSANZ and include:²

- the donor's medical history, including past health, presence of chronic disease, features of the final illness and cause of death
- the risk of transmission of malignancy, viruses such as HIV, hepatitis B, hepatitis C and other infectious agents
- factors that relate to the viability of the donor organ, such as the donation pathway (e.g. following brain death or circulatory death), ischaemic time and how the organ is preserved before transplantation.

In circumstances of donation after circulatory death, clinical interventions that support and maintain organ viability occurring before death are ethically supportable, providing there is no legal impediment and they comply with the Clinical Guidelines developed by TSANZ.

While organs available for transplantation vary in their potential benefit and associated risks, the expected benefit to the recipient must outweigh any expected risk. Only a small percentage of organs available for transplantation meet ideal clinical criteria. The anticipated benefit versus risk to recipients occurs along a spectrum and ranges from providing optimal outcomes after transplantation to a lesser benefit yet still longer survival than would be expected if the recipient remained on medical therapy. The risks associated with transplantation (e.g. poor organ survival or transmission of infection or malignancy) also occur along a continuum and are influenced by factors related to the donor, the organ and the recipient.

Characteristics of the donor organ and recipient factors all need to be weighed, including the likely benefit from transplantation of the organ on offer, urgency of need and likelihood of subsequent organ offers, and deterioration of health status while waiting for transplantation.

1.3. Broadening recipient eligibility and organ suitability criteria

Medical transplantation practice is continually improving. Increasing experience in transplantation, the availability of long-term data on outcomes and advances in technology have led to a broadening of recipient eligibility and organ suitability criteria. This approach is being used with increasing success internationally and in Australia⁵⁻⁷ and means that more organs are considered for transplantation and more individuals can benefit — essentially increasing numbers of both potential donors and recipients.

The decision to offer a person an organ occurs on a case-by-case basis, depending on the benefits and risks associated with the quality of the organ and the circumstances of the individual. Information about the type of organs that may become available for transplantation and the implications of either waiting for a more suitable organ or deciding to undergo transplantation is communicated early in the process of potential recipient evaluation and education so that an informed decision can be made at the time of any offer of an organ.

In Australia (and in the Terms of Reference for these Ethical Guidelines) different terms have been used to describe the spectrum of organ quality and that of recipient suitability.⁸ These terms are not used in this document as they imply distinct categories, rather than reflecting a spectrum and, as such, can be misleading and do not reflect the careful consideration of balance between benefit and risk when organs are considered for allocation and transplantation.

1.4. What is the process for organ allocation?

The allocation of organs is a complex and time-critical process influenced by a range of factors including medical need, urgency, donor/recipient suitability and logistical factors. There are strict Clinical Guidelines about the allocation of organs for transplantation.² The allocation system seeks to promote both utility (obtaining the best possible outcome from available organs) and equity of access to transplantation for individuals.

The organ allocation process differs according to the organ type and degree of urgency.

- When a kidney becomes available for transplantation in Australia, it is allocated to recipients according to each state's allocation formula through a computerised system called the National Organ Matching System (NOMS).

⁸ 'Standard criteria organs' — term that has been used to describe donor organs that have been assessed as providing the best overall outcomes for recipients based on donor and organ characteristics. 'Extended criteria (or higher risk) organs' — term that has been used to describe donor organs that have been assessed as presenting a higher risk to the health of recipients than standard criteria organs based on donor and organ characteristics but that would still offer greater benefit than continuing with medical therapy. 'Marginal donors' — term that has been used to describe the donors of 'extended criteria' organs. 'Alternate listing' — term that has been used internationally to describe a process by which people who do not meet eligibility criteria may be considered for organs that may not provide optimal outcomes but offer greater benefit than medical therapy alone.

Around 20 percent of kidneys are allocated outside the state of origin under the National Interstate Exchange Program to extremely well matched recipients. The remainder are allocated within the state of origin according to state-specific algorithms, which consider factors including waiting time, tissue matching, paediatric status and sensitisation. In New Zealand, kidneys are allocated through the New Zealand Kidney Allocation Scheme.

- When organs other than kidneys become available, they are offered first to transplant units in the state where the donation occurs. The allocation of these organs involves a team at the transplant unit making a clinical judgement as to which person is best suited to receive that particular organ, at that particular time. Most donated organs are allocated within their home state or territory. If no suitable recipient is identified in the state where the organ was donated, the organ is offered to transplant units in other states and territories and New Zealand.
- When an individual has a very high risk of death if they do not receive a transplant in the immediate future, he or she may be prioritised for the offer of an organ based on specific established criteria.² Urgent classification may apply, for example, to individuals with acute liver failure intubated in the intensive care unit, individuals with kidney failure for whom dialysis is no longer an option or individuals with severe heart failure who are unsuitable for mechanical support or develop life-threatening complications while on support.² In such circumstances, the individual is offered the next available compatible organ donated anywhere in Australia and New Zealand, noting that there is no system for urgent allocation of kidneys between Australia and New Zealand.

Decision-making when an organ is offered

The decision by potential recipients to accept the offer of an organ is based on their assessment of the risks and benefits as they relate to their individual circumstances. Decision-making is particularly complex when the organ being offered may have a lower likelihood of providing optimal outcomes. For example, potential recipients who are stable on medical therapy may find the expected outcomes associated with transplantation of such an organ less acceptable than would potential recipients who are advanced in age or extremely unwell who might see this as increasing their survival prospects. Thus, organs that may carry an unacceptable risk for some individuals may provide benefit for others. This balance must be decided on a case-by-case basis by the transplant team and the potential recipient.

1.5. How is the transplantation process monitored?

Data collection

Data related to organ donation and transplantation activity is essential in identifying opportunities to improve the care of donors, the donation and transplantation process, and recipient outcomes. The Australia and New Zealand Organ Donation (ANZOD) Registry, in conjunction with the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA), the Australia and New Zealand Liver Transplant Registry (ANZLTR), the Australian and New Zealand Cardiothoracic Organ Transplant Registry (ANZCOTR) and the National Pancreas Transplant Registry (NPTR), records and reports on organ donation and transplantation within Australia and New Zealand (see Appendix B).

Through this process, information is publicly available on:

- the number of organs donated by deceased donors, including comparison with international donation rates
- organ donation pathways (e.g. whether donation occurred after brain death or circulatory death, whether donation proceeded and, if not, reasons why)
- the number of people awaiting transplantation for each organ type
- the number of organs transplanted, including reasons why donated organs were not transplanted
- outcomes of organ transplantation.

The registry reports do not include any information that would allow identification of donors or recipients. However, if there is a medical necessity (e.g. an infection in a transplant recipient that could have been transmitted through the donated organ) there is the capacity for linking of the donor to the recipient(s) via transfer of medical (but not identifying) information about the donor to the transplant teams.

Governance

The data collected on donation and transplantation are used by specialist advisory committees at the federal, state and professional level to review, audit and monitor organ donation and transplantation practices.

2 Foundations

2.1. Human rights, ethical principles and values

Respect for human rights is relevant to the development and implementation of health policies, laws and practices, including those that relate to the allocation of health resources. The right to a standard of living adequate for the health and wellbeing of a person and their family has been broadly recognised in international law since the inception of the United Nations (UN). It is recognised in *The universal declaration of human rights*⁸ and has been articulated in numerous international instruments protecting the 'right to health' of vulnerable populations. The UN Committee on Economic, Social and Cultural Rights declared that people have a right to access quality health care and that states have basic duties, within the availability of resources, to provide their citizens with access to adequate and affordable health care.⁹

Human rights framework

Human rights are the basic freedoms and liberties that people are entitled to simply because they are human beings. They are expressions of respect for human dignity and of fundamental values and provide the moral basis for claims against a government, institution or individual to a particular good, service or standard of behaviour. These claims may be stated 'negatively' (e.g. as the right not to be discriminated against) or in 'positive' terms (e.g. as a right to access health care, education or legal representation).

In legal terms, modern human rights are international legal commitments in treaties to which Australia has agreed to be bound, and contain both positive obligations to protect and fulfil human rights and negative obligations to respect human rights.

Civil and political rights (such as the right to privacy and a fair trial) must be implemented immediately, with effective remedies. Economic, social and cultural rights (such as education and health) must be progressively realised and are subject to the availability of resources, except for the overarching obligation not to unlawfully discriminate, which is immediate. In Australia's legal system, human rights are legally enforceable through domestic laws where these have been enacted.

Importantly, even where human rights cannot be legally enforced or cannot be realised because of resource constraints, they retain moral significance because they are expressions of fundamental values. In this regard, consideration of human rights is important in situations involving individuals or populations who are disadvantaged in their access to basic services because it assists in the development of mechanisms to prevent discrimination and adds moral weight to their claims for access to basic services.

In addition to human rights, ethical principles and values may be used as the basis for the development and assessment of health care systems, policies and practices. These principles and values include respect, autonomy, justice, equity, solidarity, altruism, reciprocity, care and wellbeing, welfare and security, transparency, effectiveness and efficiency.¹⁰ While all of these principles and values are important, they will not always be equally important in any given situation. Judgments will always be needed as to what weight should be attached to each value and how the obligations arising from each value should be satisfied.

These principles and values may be defined as follows (their application to organ transplantation is discussed in Section 2.2).

- **Respect** — The right for all individuals to be treated with dignity and to have their autonomy respected (i.e. the right to self-determination based on an individual's particular set of values, preferences and beliefs). Respect for human dignity and worth as a characteristic of relationships between people, and in the way individuals behave, is fundamental to a functioning and ethical society.
- **Justice** — Justice is concerned with equality and fairness and is one of the core principles upon which society and its institutions (including health care systems) are based. Forms of justice relevant to the provision of health care include:
 - **distributive justice**: fair, equitable, and appropriate distribution of burdens and benefits in society determined by justified norms that structure the terms of social cooperation
 - **social justice**: the exercise of justice within a society, including recognition of causes of social inequality and the moral necessity to address them
 - **procedural justice**: fairness in the processes that allocate resources and resolve disputes, which provides a means for making health resource decisions even where there is disagreement about which principles should govern priority setting and what constitutes justice in health care.
- **Equity** — The fair distribution of benefits and burdens. For allocation of (scarce) resources to be fair, the process must be public and transparent; decisions must rest on reasons, principles and evidence that all stakeholders agree are relevant; there must be clear processes for revision and appeal; and there must be mechanisms in place to ensure each of these three conditions.¹¹
- **Solidarity** — The concept of 'standing together' as a group, community or nation, which reflects a collective commitment to share 'costs' (financial, social, emotional or otherwise) to assist others.
- **Reciprocity** — The recognition of mutual obligation between parties in a given situation.
- **Altruism** — The principle or practice of seeking the welfare of others, with no expectation of personal reward or gain.
- **Care and wellbeing** — Providing care for people and for populations and acting in ways that advance their wellbeing and interests.
- **Welfare and security** — Promoting and protecting the welfare of individuals and populations and acting in ways that avoid or minimise harm.
- **Transparency** — The open disclosure of clear and accurate information about activities and decision-making processes.
- **Effectiveness and efficiency** — The principle of **effectiveness** requires that waste is reduced, practices that clearly don't work are not used and proven measures that are likely to succeed are implemented. Effectiveness, or utility, is linked to the concept of **efficiency**, which requires that limited resources be used in the most productive manner possible.

2.2. Application of ethical principles and values to organ transplantation

The nature of organ allocation and transplantation raises a number of particular ethical issues and dilemmas, primarily because donated organs are a scarce resource that has the potential to dramatically improve the health and life of recipients. This scarcity of organs requires clear eligibility and allocation criteria to ensure a fair and equitable system for access to this limited resource.

There are many ways to justify allocating an organ to one individual over someone else, rather than just one 'right' way and differing perspectives exist on what is fair and equitable. The donor and their family, the recipient and the community in general may all have differing views about what is equitable. The decision-making process in organ transplantation should therefore ensure the balanced consideration of all relevant ethical principles, be transparent and be developed in collaboration with all major stakeholders. In this regard, it is important to note that ethical questions cannot be completely separated from social, economic, cultural and political questions and that there may be practical constraints on the achievement of an ethical principle, particularly in an area of scarce resources.

The principles and values outlined below aim to support decision-making so that, regardless of the situation, health professionals have an ethical framework to guide clinical consideration and judgment. This in turn should help to ensure that their decision-making is rigorous, consistent, transparent and supported by the community. More than one principle may need to be considered in a specific situation.

2.2.1. Donation of organs is an act of altruism, solidarity and community reciprocity that provides significant benefits to those in medical need.

Transplantation practices should be motivated by the needs of the recipient and the need to ensure the appropriate use of scarce health resources.

The availability of transplantation as a treatment to members of the Australian community is wholly dependent on the preparedness of individuals and their families to consent to donation.

The decision to donate organs is an act of extraordinary generosity. Such decisions also reflect a recognition that the continuance of a system for organ transplantation rests on the willingness of the community to support it. In other words, if we wish to have the benefits and security provided by a viable and equitable transplantation network (both for ourselves and for others) then we should, ourselves, be prepared to consider organ donation.

Organs donated for transplantation must be obtained without exploitation or coercion of, or payment to, the family of a deceased donor. It is unethical and unlawful to purchase, offer to purchase or sell organs for transplantation.³

2.2.2. Processes and policies for determining a person's eligibility for transplantation and for allocating donated organs must be just, equitable and respectful of the inherent dignity and of the equal and inalienable rights of all persons.

Decision-making about allocation must include explicit evaluation of the risk and benefits to the potential recipient as well as the need to ensure the appropriate use of scarce health resources.

There must be no unlawful or unreasonable discrimination against potential recipients on the basis of: ^{2,12}

- race, cultural and religious beliefs, gender, relationship status, sexual preference, social or other status, disability or age
- need for a transplant arising from the medical consequences of past lifestyle
- capacity to pay for treatment
- location of residence (e.g. remote, rural, regional or metropolitan)
- previous refusal of an offer of an organ for transplantation
- refusal to participate in research.

The choices of potential recipients should be respected, including those based on religious or spiritual beliefs or cultural heritage with regard to the acceptability of organ transplantation, or specific medical procedures or treatments required for transplantation. However, when such choices are likely to have an adverse effect on the success of the transplantation, it is appropriate that this is taken into account in the decision-making regarding the offer of an organ for transplantation.

Respect should be given to the expertise and opinion of health professionals as they make decisions relating to organ transplantation, involving complex issues, often in urgent situations.

2.2.3. Decision-making about transplantation must recognise and respect the autonomy of the recipient.

As for all medical procedures, consent must be given before transplantation can proceed. The process of seeking and receiving consent should be sensitive to an individual's particular set of values, preferences and beliefs that may affect decision-making.

If the individual does not have capacity to give consent, a representative should be involved in ongoing discussions and decision-making. For consent to be valid:

- the decision to consent to the procedure must be made without undue pressure from health professionals, family and friends
- sufficient information about the procedure must be made available, including the risks and benefits and what will

happen if the procedure does not go ahead — health professionals should not withhold information just because it may be upsetting

- the consent must be specific and is valid only in relation to the procedure for which information has been given
- the person giving consent must be considered by the treating clinician to have the capacity to provide consent.

2.2.4. The allocation and transplantation of organs must be undertaken in a manner that protects recipients from harm.

Organ transplantation should only be undertaken when it is believed that it provides a benefit to the recipient.

Decisions regarding the transplantation of organs should take into account the condition of the organ as well as the general health and medical need of the recipient and the likelihood of a successful transplantation outcome balanced against the risk of not receiving a transplant.

An individual's psychological and physical wellbeing should be supported as far as possible throughout the process. This may include referral for psychosocial support, medical interventions or treatments (e.g. dialysis, the use of medical devices such as ventricular assist devices) and appropriate support to adhere to the necessary ongoing treatment and health advice after transplantation.

2.2.5. The process of allocating and transplanting organs should acknowledge both the needs and wellbeing of the recipient and the necessity to achieve the best outcome for the community as a whole.

Predictions about the likelihood of benefit arising from a transplant are often difficult and uncertain, with some factors being subjective in nature. Such predictions and the uncertainty around them should be conveyed to the potential recipient as part of the process of seeking consent.

Decisions should take into account the views of the individual about expected outcomes and should not deviate from established clinical criteria. Factors that should be considered include:

- the needs of the individual and the potential benefit to the individual
- the need to ensure the appropriate use of scarce health resources
- the risk of the transplantation process balanced against the benefits to the recipient
- pretransplant quality of life, expected extended length and quality of life and duration of benefit
- medically relevant criteria related to the recipient and the organ to be transplanted.

2.2.6. The organisation and implementation of transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

Criteria used for decision-making about eligibility of potential recipients and suitability and allocation of organs for transplantation must be transparent and made publicly available.

Detailed records must be maintained so that the long-term outcomes of organ donation and transplantation can be assessed. The objectives of the system are to maximise the availability of data for research, monitoring and professional oversight and to identify risks — and facilitate their correction — in order to minimise harm to donors or recipients.

Processes must be in place for audit and peer review of clinical decisions.

Conflicts of interest

Transplant physicians and surgeons should not be involved in decision-making about end-of-life care or determination of death of individuals who may become organ donors.

Health professionals should not be involved in decision-making when family members, friends or colleagues are prospective donors or recipients.

Decisions about the eligibility of an individual to receive an organ should be made by the multidisciplinary transplant team, rather than the individual's physician. In some cases, involvement of a clinical ethics committee may be required.

Privacy

Health professionals and institutions must respect the privacy of donors, recipients and their families, maintain confidentiality of all records and comply with relevant legislation and guidelines.

Health professionals have a responsibility to counsel and advise recipients and their families about the potential consequences of releasing information about the procedure (e.g. through social media).

Recipients have a responsibility to respect the privacy of the donor and their family and to not release information that will potentially identify the donor. Donor families have a responsibility to respect the privacy of recipients and their families and to not release information that will potentially identify recipients.

3 Ethical practice

The ethical principles and values outlined in Chapter 2 must inform:

- discussions about transplantation
- determining eligibility for organ transplantation
- assessing donor organ suitability
- allocating organs.

This section highlights specific issues to be considered in these situations. Constraints on the implementation of an ethical principle are also discussed, recognising that these may change over time.

3.1. Discussing transplantation

The nature of organ transplantation is unpredictable and often involves the need for both the potential recipient and the health professionals to make complex and urgent decisions. Critical decision points include when eligibility is being discussed and the time when an organ becomes available.

Discussions about transplantation between the physician and the potential recipient should begin well before an organ becomes available and be ongoing throughout treatment. Potential recipients need to be made aware that their consent to transplantation will take place through an ongoing series of discussions about risks and benefits, which may ultimately lead to the individual recipient's decision to accept the offer of an organ for transplantation. Recipients should also be informed that they may withdraw their consent to transplantation at any stage before the procedure.

Information about the variation in quality of donor organs needs to be provided to the potential recipient early in the process so that they are well-prepared to make a decision about whether to accept the offer of a particular organ in the limited time available.

When an organ is offered, more specific information about the particular organ and the risks and benefits of transplantation relevant to the potential recipient's clinical circumstances should be provided to the recipient.

Relevant information should be provided in a manner that is likely to be understood by the potential recipient and others involved, appropriate to their needs and particular situation and sensitive to any religious, cultural and spiritual differences that may affect decision-making.

As part of ongoing discussions about transplantation between potential recipients and members of the multidisciplinary team the following information should be provided.

- Potential recipients may wait varying periods of time for a suitable organ to become available. This waiting time will be dependent upon a suitable organ becoming available.
- When deciding whether to accept the offer of an organ, there is a need for recipients to balance the risks and benefits of their specific circumstances, including:
 - their expected outcomes following transplantation compared to continuing with medical therapy
 - individual factors that affect their likelihood of a successful outcome (e.g. the presence of other medical conditions and their likely ability to adhere to treatment after transplantation)
 - known factors related to the organ being offered.

- The information that will be provided to the potential recipient about the risks and benefits associated with transplantation of a particular organ is based on population statistics. As for all population-based data, there is uncertainty as to how these data will apply to the individual. All procedures carry some element of risk and it may be difficult to quantify risks and benefits at the individual level.
- As rapid decision-making is needed when an organ becomes available, it is important for the potential recipient to be informed of and to consider a range of scenarios well in advance of an organ offer being made.

Discussions should also include treatment while awaiting transplantation and the recipient's wishes for end-of-life care should a suitable organ not become available.

Decision-making by potential recipients

The process of decision-making should be conducted in consultation with the potential recipient and/or their representative. The potential recipient's partner, family and/or carer should ideally be involved in discussions, as the success of a transplant is greatly dependent on the recipient's support network following transplantation. Relevant information should be provided in a manner that is likely to be understood by the potential recipient and others involved, appropriate to their needs and particular situation and sensitive to cultural and spiritual differences that may affect decision-making. Individuals have the right to determine the amount of information that they require to make decisions, within the limits of the time available.

Consideration must be given to a potential recipient's ability to understand the information and to provide consent.

While it must be assumed that all adults have capacity to make decisions about their own health care and to provide consent, it is always important to make certain that potential transplant recipients:

- have the capacity to make their own health care decisions
- are supported in their decision-making
- make decisions in a free and voluntary manner.

Sometimes, it may be difficult to determine an individual's capacity to provide consent. In these situations, health professionals with the skills to assess this capacity must be included in the multidisciplinary team involved in the care of the individual.

Adults with impaired decision-making capacity

It should not be assumed that adults who are intellectually impaired or have mental illness are incapable of giving consent. Individuals who have the ability to understand and retain information and to weigh that information to arrive at a decision may have capacity to give consent.

If an adult is considered to lack capacity to give consent, a representative (such as a 'person responsible' or a guardian) should be involved in early discussions about eligibility and decision-making about proceeding with transplantation. The person's representative should be involved in substituted, facilitated or supported decision-making depending on whether incapacity is permanent, temporary, partial or intermittent (e.g. due to the effects of the progression of the disease).

Even when individuals are judged to lack capacity to make decisions regarding transplantation, they should be encouraged, to the extent possible, to be involved in decision-making.

All Australian states and territories have enacted guardianship legislation that deals with consent to the treatment of adults who lack capacity to consent on their own behalf (see Appendix B). This legislation promotes the autonomy of the represented person and/or safeguards the person's best interests.

Children

It is very important that a child who is being considered for organ transplantation is helped to understand the transplantation process as thoroughly as possible, consistent with age and maturity. As children mature they will have a greater capacity for understanding and a clearer appreciation of the significance of their own decisions. Therefore, although legally still minors, older children should be encouraged to take an active part in decision-making

(see *Adolescents* below).

The parent(s) or guardian(s) must provide consent for transplantation for children. Specific legislation regarding the capacity of children to consent to medical procedures exists in some jurisdictions (see Appendix B).

Adolescents

It is recognised that the capacity of adolescents to make decisions about treatments does not follow chronological age and that the capacity among adolescents aged 16 years and younger varies between individuals. If a person in this age group achieves a sufficient capacity to enable full understanding of what is proposed, they may be considered capable of giving consent (described as 'Gillick competence', which has been approved by the Australian High Court).¹³ More rigorous criteria may need to be applied in assessing an adolescent's capacity to refuse treatment and a court or tribunal may need to be involved.

Even when young people are judged to lack sufficient maturity to make independent decisions regarding transplantation, they should still be actively involved in the decision-making process, be supported to understand the situation they are in and what is being proposed and, where possible, *assent* to transplantation.

In the adolescent age group, the capacity to provide consent should be determined on an individual basis. Responsibility for determining this capacity rests with the multidisciplinary team involved in the care of the individual.

Individuals from culturally and linguistically diverse backgrounds and Aboriginal and Torres Strait Islander people

It is important for members of the multidisciplinary team involved with assisting potential recipients in making decisions about organ transplantation to have an understanding of the cultural and linguistic background and beliefs of the individual involved, including any issues specific to Aboriginal and Torres Strait Islander people. Cultural awareness can also assist members of the multidisciplinary team to respond appropriately to any questions or concerns and help potential recipients, their families, carers and friends faced with difficult decisions to be better prepared, should the situation arise.

Information provided to the potential recipient should be appropriate to their cultural and linguistic background.

People with appropriate training and experience should be available to the individual and members of the multidisciplinary team throughout the transplantation process, both to enable consent and to optimise care; for example, Aboriginal Health Workers or Aboriginal Hospital Liaison Officers; an appropriately qualified interpreter if the potential recipient does not speak English.

3.2. Ethical decision-making in the context of transplantation

3.2.1. Eligibility for transplantation

In assessing an individual's eligibility for transplantation, the multidisciplinary team should be guided by the values and principles outlined in Chapter 2.

Decisions regarding eligibility for organ transplantation must exclude unlawful or unreasonable discrimination on medically irrelevant grounds and ensure that medically relevant factors are carefully assessed. As outlined in Section 2.2.2, there must be no unlawful or unreasonable discrimination against potential recipients on the basis of:^{2,12}

- race, cultural and religious belief, gender, relationship status, sexual preference, social or other status, disability or age
- need for a transplant arising from the medical consequences of past lifestyle
- capacity to pay for treatment
- location of residence (e.g. remote, rural, regional or metropolitan)
- previous refusal of an offer of an organ for transplantation
- refusal to participate in research.

While registration on the Australian Organ Donor Register is desirable and encouraged, it does not influence decision-making regarding eligibility for transplantation for ethical reasons (e.g. inequity of access for people who are unable to become donors for medical reasons and the potential for coercion).

It is ethically acceptable for the following factors to be taken into account when considering eligibility for transplantation:

- relative severity of illness and disability and urgency of the need for transplant (e.g. imminent death)
- general health including factors that will directly affect the likelihood of a poor outcome, such as degree of frailty and relevant medical conditions
- reasonable likelihood that the recipient will be able to adhere to the necessary ongoing treatment and health advice after transplantation.

Individuals assessed for eligibility for transplantation have the right to know whether or not they are considered suitable and, if they are evaluated as being ineligible for transplantation, the basis for this decision.³

Case study 1

A 14-year-old girl with cerebral palsy uses a wheelchair, has language delay and is incontinent. She is neurologically stable and perceived by her parents to have a good quality of life. It is anticipated that she will survive beyond early adulthood. However, her kidney function is declining and she is currently receiving dialysis. Her eligibility for kidney transplantation is now being considered.

- Kidney transplantation would provide the girl with health benefits over dialysis. It would also provide benefits in terms of quality of life for the whole family, including more family-based care, less travel for dialysis attendance and reduced financial burden.
- When making a decision about this girl's eligibility for transplantation, her disabilities are not relevant unless they are related to medically relevant factors. Determining her eligibility based solely on the presence of her disabilities would be discriminatory.
- This girl would likely be a candidate for transplantation. However, the final decision must be made by a multidisciplinary team.

Case study 2

A young woman with bipolar disorder has been referred for assessment for a kidney transplant.

- Mental health conditions are among the medical conditions assessed by the multidisciplinary team in determining eligibility.
- Considerations include whether the woman's bipolar disorder is being adequately managed, whether she has the capacity to give consent, her ability to adhere to ongoing treatment and health advice after transplantation and the social support available to her.
- In this case, the decision by the multidisciplinary team should be informed by advice from a psychiatrist and/or a social worker.

Case study 3

A 42-year-old man is currently being assessed for a heart transplant. He has a history of amphetamine use and repeatedly claims to have stopped using amphetamines over 12 months ago. However, laboratory tests confirm recent amphetamine use. Apart from his heart condition he has no other medical conditions. His heart condition is now rapidly deteriorating and an urgent decision needs to be made.

- Active substance abuse excludes people from being considered as eligible for heart transplantation.²
- While he is in urgent need of a transplant, his current amphetamine use (confirmed by blood testing) means that he is more likely to have a poorer outcome following transplant and he is less likely to be able to adhere to the necessary ongoing treatment and health advice after transplantation.
- Given his confirmed amphetamine use, this man is not currently eligible for a transplant despite the urgency of his need.

Case study 4

A 63-year-old man has end-stage kidney disease and has been on dialysis for 5 years. His condition is rapidly deteriorating. He also has another chronic condition that may contribute to poor outcomes following transplantation. This means that his chances of being offered an organ are low. His transplant team explains to him that he could choose to accept an organ that does not meet ideal criteria for transplantation but which could provide him with an increased opportunity for transplantation.

- Transplantation is likely to provide the man with greater health benefits than remaining on dialysis and increase his life expectancy.
- Considerations include the man's ability to manage his other chronic condition and to adhere to treatment and lifestyle advice after treatment.
- The man would need to weigh the risk and benefits involved in being prepared to accept such an organ against the possibility of further deterioration of his condition.

Retransplantation

Ethical decision-making about eligibility for organ retransplantation should be based on the same criteria as for the initial transplant. However, the post-transplant history and previous adherence to treatment and health advice are relevant considerations. The outcome of this decision-making may mean that a person may be offered a second transplant ahead of another individual who has yet to receive a transplant.

Combined organ transplantation

There are times when individuals require combined organ transplants (e.g. heart-lung, heart-kidney or heart-liver). While in such cases ethical decision-making about eligibility is the same as for single organ transplantation, the evaluation of these individuals is more complex because it requires detailed assessment and agreement by both organ transplant teams that all eligibility criteria are met.

While the transplantation of two organs into one person may raise issues of equity — as two people could benefit from transplantation instead of one — the medical need of the potential recipient must be respected in the same way as those requiring single organ transplants.

Process of review

There must always be a process for an impartial review of decisions relating to eligibility for transplantation. The process should be independent and conducted in a timely and transparent manner. Medical records and the results of tests and other investigations relevant to the individual's situation should be made available to facilitate a second opinion. A second-tier review committee at state level may be involved in reviewing the decision.

The review should assess the processes followed in reaching the decision as well as the clinical basis for the decision.

3.2.2. Organ allocation

Decisions about organ allocation should be guided by the values and principles outlined in Chapter 2.

The allocation of organs for transplantation should be based on established clinical criteria, with the aim of achieving the best overall outcomes for the recipient and the appropriate use of a scarce resource. The process of allocation should be equitable, externally justified, transparent and explained to recipients and their families. Allocation of organs should proceed based on urgency of need and identification of the potential recipient who is most appropriate to receive a particular organ.

Consideration should also be given to maximising the benefits of each available organ. For example, high quality livers may be suitable for splitting and able to provide the benefit of transplantation to two recipients (usually an adult and a child).

Allocation of organs is a complex process that depends on a range of factors besides general health, medical need and capacity to benefit. There are unpredictable elements in the process that relate to the timing of an organ becoming available and the allocation of organs to recipients.

Decisions about the allocation of organs for transplantation should exclude unlawful or unreasonable discrimination based on factors that are medically irrelevant (see Section 2.2.2). Medically relevant factors must be carefully assessed and arbitrary refusal of the offer of an organ by transplant clinicians must not occur.

It is legitimate that, as well as the ethical principles outlined in these Ethical Guidelines, the following criteria be taken into account when considering potential recipients for a particular organ:¹²

- urgency of a transplant given the likely deterioration of health without transplantation, especially if the survival of the potential recipient is immediately threatened
- length of time waiting for a transplant, taken from the time that illness progressed to a point that a transplant would be of immediate benefit
- risks of transplantation weighed against the potential benefits to the recipient
- general health including medical factors that will affect the likelihood of success, such as the closeness of tissue-matching and organ quality with the potential recipient's medical status

- the prospects of transplantation producing a better outcome than medical therapy alone
- the likelihood that the potential recipient will be able to adhere to the necessary ongoing treatment and health advice after transplantation.

For transplantation involving vascularised composite tissue allografts, such as face and hand transplantation, aesthetics may be a valid consideration. For example, it may be appropriate to consider age, gender and skin colour of donor and recipient.

By its nature, the allocation process is very difficult to follow with absolute equity. Multiple factors are involved and this can make clinical decisions about allocation very difficult. Every attempt should be made to provide the best judgement upholding the principles outlined above. A process of audit and peer review of clinical decisions must therefore be in place.

Case study 5

A donor heart is suitable for two individuals awaiting transplantation. One potential recipient is a 20-year-old man whose first transplant is failing after 10 years. He is now in urgent need of a transplant. The other is a 35-year-old man awaiting a first transplant, whose clinical condition is stable.

- The fact that one individual has already had a transplant must not influence the decision about which individual to transplant.
- This decision must be made based on clinically relevant factors, which can include the reasons why the transplant is failing, clinical condition of potential recipients and the time interval since the first transplant.
- In this case the decision is made to retransplant the younger man due to his deteriorating clinical condition.

Case study 6

A liver has become available that is suitable for two people.

Scenario A

A woman requires a transplant as a result of alcoholic liver disease. She currently lives with her elderly parents.

- The fact that the woman requires a liver transplantation due to alcoholic liver disease is not a relevant factor in determining allocation of organs. Discrimination against potential recipients on the basis of the cause of the illness is unethical.
- Decision-making about the allocation of the liver should take into account the woman's social situation and the likelihood of her continuing to abstain from alcohol following the transplant and adhering to post-transplant treatment. These factors are clinically relevant to the success of the transplant.
- It is very difficult to predict with absolute certainty the way individuals will cope with post-transplant therapy, abstinence and other lifestyle changes.
- Throughout the transplantation process, the multidisciplinary team should engage the woman and her parents in discussions about the importance of adhering to ongoing treatment and lifestyle advice following transplant.

Scenario B

A man requires a liver transplantation but is not willing to consent to a blood transfusion.

- While individual beliefs and values should be respected, in the case of organ transplantation the right to self-determination needs to be balanced against the right of the transplant team to decide not to proceed on medical grounds.
- The man should be counselled by the transplant team about the medications and treatments, including the need for blood transfusion, that are required for the transplant to be successful and the reasons why this is the case.

- If the man will not consent to the full range of treatments required for transplantation, the transplant team can make a decision not to proceed on medical grounds.

In both scenarios the multidisciplinary teams have an ethical obligation to ensure the best possible use of a scarce resource such as donated organs. They need to have ongoing discussions with potential recipients and provide education and information about the effect of choices on the outcomes of transplantation.

Accepting the offer of an organ for transplantation

When the offer of an organ is made, the transplant team should provide appropriate information to the potential recipient or their representative to assist them in their decision-making.

Discussion should take into consideration the individual's current quality of life, likelihood of survival without immediate transplantation and the risks and benefits associated with transplantation of the organ being offered, as far as these can be predicted.

A potential recipient or their representative must give consent before transplantation can proceed (see Section 3.1).

Case study 7

A kidney is available that was donated by a 52-year-old man with a history of hypertension who died following a stroke. The older age of the donor is a consideration in assessing suitability of recipients.

Scenario A

The kidney may be suitable for a 25-year-old woman who has been on home dialysis and waiting for a transplant for 6 years. Her condition is currently stable.

- In making her decision the woman will need to balance the risks and benefits of accepting this kidney, including the expected survival of the kidney and her own expected survival time following transplantation, as well as the risks and benefits of her remaining on dialysis rather than accepting the kidney.
- On balance, given her health status, the risks associated with transplantation of this kidney exceed those of continuing to wait for another organ. These include the risk of failure of the kidney after transplantation and the consequent likelihood of requiring retransplantation sooner.
- The woman may accept the risk of waiting for another kidney to become available.

Scenario B

The kidney may be suitable for a 69-year-old man who has been on dialysis and waiting for a transplant for 2 years. His condition is deteriorating and he is unlikely to be considered eligible for transplantation for much longer.

- A kidney from a younger donor without a history of hypertension would likely provide a better outcome than the kidney being offered. However, the man has a poor prognosis on dialysis and his likelihood of death without a transplant is high.

In both scenarios, members of the multidisciplinary team should have prepared the potential recipient for this situation at the time he or she was considered eligible for transplantation, as the decision to accept the risks associated with transplantation of the kidney will need to be made as a matter of urgency once the offer is made.

Case study 8

A 40-year-old woman requires a liver transplant because of liver cirrhosis and related hepatocellular liver cancer. The hepatocellular liver cancer is enlarging despite specific treatments and, if it grows much larger, transplantation will no longer be an option. Her transplant team explain to her that, because of the urgency of her situation, she may be offered an organ that is sufficiently compatible to save her life but may not meet ideal clinical criteria for transplantation.

- The woman needs to be prepared for the possibility of being offered such an organ because, if such an offer is made, she will need to make a decision quickly.
- The woman would need to weigh the risks and benefits involved in accepting the organ.

Case study 9

A 32-year-old woman has a cognitive impairment and lives with her parents, who are her carers and guardians. The woman has end-stage kidney disease, which is being managed through home dialysis and medication given to her by her parents, and has been assessed as eligible for a kidney transplant. A kidney is now available that is suitable for her.

- As the parents are the woman's guardians, they would be involved in decision-making and provision of consent.
- A primary consideration is whether the woman will have the ability to adhere to ongoing treatment following transplantation either by herself or with the assistance of her parents.
- In this case, the parents have experience and demonstrated ability in administering medications and adhering to treatment regimens and transplantation can proceed with their consent.

Case study 10

A man with Down syndrome and associated congenital heart disease is in need of a lung transplant. There is concern about the man's ability to provide consent for transplantation.

- It should not be assumed that this man is incapable of giving consent.
- However, as it is difficult to determine his capacity to give consent, the multidisciplinary team involved with his care must include people with the skills to assess this capacity.
- If it is established that the man does not have the capacity to give consent, a representative must be involved throughout all stages of the process, including early discussions about eligibility and subsequent decision-making about proceeding with the transplant.
- This representative would then provide consent for the transplantation.

Case study 11

A 15-year-old girl has been assessed as eligible for a kidney transplant. An offer of a kidney is made and her parents are keen for her to have the procedure and give their consent. However, the girl refuses to have the transplant surgery. The girl has expressed an understanding of the nature of the procedure and the need for ongoing medical therapy following transplant.

- Discussions should ensure that the girl has full information about the consequences of not proceeding with the transplant, including the long-term risks and benefits of her current treatment.

- As the girl has demonstrated an understanding of the risk and benefits of the surgery as well as not proceeding with the transplant, she should be considered capable of giving consent and her autonomy regarding her decision should be respected.
- The multidisciplinary transplant team has an obligation to ensure that the decision about transplantation is revisited at a later point in time as the girl matures, as this may affect her initial decision not to proceed.
- It may be necessary to involve an independent advocate to assist in resolving any conflicts between the wishes of the girl and those of her parents.
- Early inclusion of the girl in discussions about potential transplant would have helped to build trust and discover points of disagreement well in advance of the offer of an organ.

Deceased directed donation

The donation of deceased donor organs in Australia is an unconditional altruistic act. Deceased donor organs are allocated to the most suitable people as outlined above. It is not ethically appropriate for a donor, through previously expressed wishes, or the family of a deceased person to impose conditions on organ donation or to specify potential recipients.

It may be ethical for deceased directed donation to occur when:

- there is evidence that the person was prepared to be an organ donor after death
- there is evidence (e.g. through a living will, advanced care directive or prior planning with a transplant team) that the person expressed a preference for certain organs to be donated to a close relative in need of a transplant
- the potential recipient is considered eligible for transplantation and consents to receiving organs from that donor.

Case study 12

Scenario A

A woman has offered to donate a kidney to her daughter. However, the woman is not considered to be a candidate for living donation on medical grounds and is advised that the donation cannot proceed. When the woman is admitted to an intensive care unit and assessed as meeting criteria for loss of all brain function, her partner advocates for the daughter to be transplanted with a kidney from the mother.

- As there is evidence that the woman had wished to donate her kidney to her daughter before her death, the woman's wish may be honoured.

Scenario B

A man has been accepted as a living donor so that he can donate part of his liver to his daughter. However, before the living donation is able to occur, the man is admitted to intensive care and is assessed as meeting criteria for loss of all brain function. The man is a registered organ donor and his family agrees that his organs should be donated after death. They have requested that part of his liver be donated to the daughter as was the intention before his death.

- As the man had already been accepted as a living donor for his daughter and as his untimely death was the only reason that this did not occur, the man's intention to donate part of his liver to the daughter may be honoured.

In both scenarios the other donated organs must be allocated to the most suitable recipients in accordance with established procedures.

Case study 13

A young man in an Intensive care unit meets the criteria for donation after brain death. His family agree for his organs to be donated but only to people of the same religious faith as the family. If this is not possible, they will not agree to organ donation going ahead.

- It is not ethically acceptable for conditions to be placed on the donation of organs as it undermines the altruistic nature of organ donation.
- In this case, if the family will only agree to the conditional donation of organs, organ donation cannot proceed.

Issues of access

Every Australian who would benefit from an organ transplant should be provided with an opportunity for assessment to receive one. In practice, however, there may be some issues that constrain the ability of transplantation units to provide absolute equality of access in the allocation process. These include:

- **costs** — in some limited circumstances an otherwise suitable organ is not able to be transplanted due to the costs of transporting the organ and/or relocating the recipient
- **population size variations** — the difference in population between the states means that some have the potential for higher numbers of donated organs (this is in part addressed by the system of providing access to organs that cannot be allocated within the state of donation through a national organ rotation and allocation system)
- **people living in rural and remote areas** — access for those who live in rural or remote areas may be affected by either their willingness and ability to relocate closer to the transplant unit and/or the provision of adequate logistic assistance and accommodation and transport to enable them to do so.
- **people in correctional institutions** — difficulties may occur when correctional services are not able to transport recipients within the necessary timeframes or to ensure provision of post-transplant care.

Case study 14

An Aboriginal man has been assessed as eligible for a kidney transplant. The man lives in a remote area of Australia which raises particular logistical issues. A suitable kidney becomes available.

- Throughout the discussions about transplantation, and at the time when the man is making a decision about whether or not to accept the offer of the kidney transplant, an Aboriginal Health Worker/Hospital Liaison Officer has been involved in the discussions between the man, his family and the multidisciplinary team.
- All information provided to the man and his family, both verbally and written, has been appropriate to their cultural background and includes information about the logistical issues that will be made so that he can travel to the hospital to receive a transplant as well as post-transplant treatments.

International visitors

In view of the existing gap between donor organ need and availability, only in exceptional circumstances should people who are not Australian citizens or permanent residents be assessed for possible transplantation.

Transplantation may be necessary if an international visitor develops acute organ failure, where the only therapy is transplantation and the visitor is too unwell to return to their home country. In this situation, it would need to be established that the visitor would return to an environment that permits appropriate ongoing post-transplant surveillance and treatment.

3.3. Ethical decision-making in innovative transplantation practice and research

Ongoing awareness of developments in medical technologies is integral to understanding and utilising the best options available to the Australian community. There are scientific developments and research on the horizon that will challenge current accepted clinical and ethical practice in donation and transplantation. The Australian community needs to be prepared to deal with the ethical issues that may arise in relation to any evolving technology and techniques in organ transplantation and the transition from research and innovation to established practice.

The disparity between the availability of donor organs and the number of individuals in need of transplantation highlights the importance of continually refining and developing new transplantation methods, processes and techniques that may allow for the better utilisation of organs, or that better prepare individuals for transplantation.

Developments in the field of organ transplantation such as machine (or *ex vivo*) perfusion of organs have the potential to transform and increase the opportunities for individuals needing a transplant.⁵⁻⁷ Repair and regeneration of organs will have a substantial impact on the number of suitable organ donors. Both mechanical and biological (stem cell) organ replacement therapies may also change the profile of people needing an organ transplant.^{14,15}

While many innovations may not have been fully assessed for safety and/or efficacy before they are used in clinical practice, it is important to note that innovative practice occurs on a spectrum. At one end of the spectrum small changes may be made around the edges of established practice over many years. Such changes may pose little risk to patient safety. At the other end of the spectrum are new and possibly revolutionary procedures that may ultimately transform the organ transplantation landscape. Such practices are part of clinical research and should be undertaken in line with an ethically approved protocol.

Whether an individual's treatment is innovative clinical practice or is clinical research will often depend on the extent to which the procedure is departing from established practice. For instance, increasing donor age limits is an example of an innovative practice that would usually be a matter for the responsible health professional's judgement, guided by clinical guidelines.² Even so, the implementation of a new innovative practice would require notification to the hospital where the practice is taking place and the collection of data for monitoring and reporting purposes, to determine whether it can become part of standard clinical care.

The following points are intended to guide ethical decision-making and practice when considering innovative techniques.

- Innovative transplantation practices should be informed, where possible, by international experience.
- Processes for reviewing innovations in transplantation practice should be in place (such as keeping data on outcomes at a national level) and must be notified to the hospital.
- The potential for improved quality of life following innovative procedures must be balanced against the short- and long-term risks to the recipient, including those that are not yet known about the innovative practice.
- While it is expected that innovative practices may challenge established constructs, they must be shown to offer improvements in outcomes before established practice is questioned.
- Where a proposed intervention is innovative and/or experimental, this must be made clear to the potential recipient as part of the process of consent, along with the risks and benefits that accompany the procedure.
- As newly developed practices and procedures are associated with limited understanding of the long-term physical and psychological outcomes, continuing monitoring of the recipient following an experimental or innovative procedure is of particular importance.

There are times when the boundary between innovation in clinical practice and research is not clear. If there is any doubt about whether the innovation constitutes research, advice from a Human Research Ethics Committee should be sought.

Case study 15

A 57-year-old woman with end-stage heart disease has been assessed as eligible for a heart transplant. However, her condition is deteriorating rapidly and her death is imminent. It is unlikely that a suitable heart will become available for transplantation in the near future. The woman is advised by her transplant team of the possibility of her receiving a heart transplant from a donor who has died after circulatory death, as part of a trial of a new procedure.

- Current clinical practice in heart transplantation uses organs donated after brain death. Hearts are not donated for transplantation when the donor has died after circulatory death as there are risks associated with using these hearts, including the possibility of severe damage occurring to the heart after circulatory death and difficulties in preserving and assessing the viability of the heart once circulation has ceased.
- In this instance, the trial that has been recommended to the woman involves the use of innovative practices that have been shown experimentally to enhance preservation of hearts donated after circulatory death and enable assessment of their viability between the time of donation and that of transplantation.
- The trial has been approved by the hospital's Human Research Ethics Committee and the technique used in the trial has resulted in successful outcomes for a number of Australian recipients.⁶
- In discussions with her transplant team about this option, the woman will receive full information about the trial and the risks and benefits of her participation. She must meet certain eligibility criteria. Once all the information has been provided, consent from the woman is required before she can be recruited into the trial.

Given her personal circumstances, the woman decides to participate in the trial. She understands the risks involved in participation and considers that, even if the treatment she receives does not prolong her life, it may provide valuable information for the future success of this new and innovative treatment.

Note that, while transplantation of hearts donated after circulatory death is an example of innovative practice at the time of development of this document, there is an expectation that this will become established practice before this document is reviewed.

Appendices

A. Terms of reference and membership of the Expert Advisory Group

Terms of reference

The Expert Advisory Group will be established to advise on the development of the *Ethical guidelines for eligibility criteria and allocation protocols for organ transplantation from deceased donors*.

In developing its advice the Expert Advisory Group will:

- Consider ethical issues relating to eligibility criteria for entry onto organ transplant waiting lists; donor suitability criteria for organ allocation for transplantation; and the organ allocation protocols for determining transplant recipients. At a minimum this will include issues identified in development of the 2011 TSANZ Consensus Statement² Version 1.2 including:
 - use of likelihood of survival as an eligibility criterion for entry on transplant waiting lists;
 - the process of alternate listing for matching extended criteria donors with extended criteria transplant recipients;
 - access to transplantation for rural and regional patients;
 - ethical principles to guide criteria for retransplantation;
 - ethical principles to guide the balance of criteria relating to utility and equity for entry onto transplant waiting lists and allocation protocols for determining transplant recipients;
 - ethical principles to guide criteria for access to transplantation by international patients;
 - ethical principles to guide consideration of an appeals mechanism relating to clinical decisions about entry onto transplant waiting lists;
- consult with key stakeholders and consider feedback from consultations;
- develop final advice in the form of draft ethical guidelines for consideration by the Australian Health Ethics Committee;
- make any consequential recommendations to AHEC in relation to the currency of the current NHMRC Ethical Guidelines:
 - *Organ and tissue donation after death, for transplantation - Guidelines for ethical practice for health professionals* (2007);
 - *Making a decision about organ and tissue donation after death* (2007).

Membership

Member	Area of expertise
Professor Ian Olver AM (Chair)	Chair, Australian Health Ethics Committee
Ms Diana Aspinall	Member with community/consumer expertise with a background in transplantation, donation and/or health ethics
Professor Steve Chadban	Member with expertise in kidney transplantation, nominated by the Transplantation Society of Australia and New Zealand
Professor Jeremy Chapman	Member with expertise in kidney transplantation, nominated by the Transplantation Society of Australia and New Zealand
Professor Jonathan Fawcett	Member with expertise in liver transplantation, nominated by the Transplantation Society of Australia and New Zealand
Professor Kirsten Howard	Member with expertise in community preferences for health care interventions
A/Professor Ian Kerridge	Member from Australian Health Ethics Committee with expertise in medico-legal and/or health ethics
Professor Peter Macdonald	Member with expertise in heart transplantation, nominated by the Transplantation Society of Australia and New Zealand
Professor Geoffrey McCaughan	Member with expertise in liver transplantation, nominated by the Transplantation Society of Australia and New Zealand
Ms Eva Mehakovic	Member with expertise in deceased donation policy, nominated by the Organ and Tissue Authority
Dr Stewart Moodie	Member with medical expertise in deceased donation, nominated by the Australian and New Zealand Intensive Care Society
Mr David O'Leary	Member with community/consumer expertise with a background in transplantation, donation and/or health ethics
Dr Helen Opdam	Member with medical expertise in deceased donation, nominated by the Australian and New Zealand Intensive Care Society
Mr Paul Robertson	Member with clinical expertise in deceased donation, nominated by Australian Transplant Coordinators Association
Professor Loane Skene	Member from Australian Health Ethics Committee with expertise in medico-legal and/or health ethics
Professor Greg Snell	Member with expertise in lung transplantation, nominated by the Transplantation Society of Australia and New Zealand
Dr Helen Watchirs	Member with community/consumer expertise with a background in transplantation, donation and/or health ethics

B. Further sources of information

Further information about donation and transplantation

Transplantation units and hospitals have their own information relevant to transplantation, which will be based on these Ethical Guidelines and the Clinical Guidelines. Information is also available from the Organ and Tissue Authority Organ and Tissue Authority (see www.donatelife.gov.au/frequently-asked-questions) and the Transplantation Society of Australia and New Zealand (see <http://www.tsanz.com.au/organallocationprotocols/index.asp>).

International guidance on ethics and organ transplantation

Eurotransplant. Ethical charter for Eurotransplant International Foundation. 2011. (www.eurotransplant.org/cms/index.php?page=newsitems&action=viewitem&oid=458&id=1641).

Participants in the International Summit on Transplant Tourism and Organ Trafficking. The declaration of Istanbul on organ trafficking and transplant tourism. *Exp Clin Transplant* 2008 Sep;6(3):171–79.

The Madrid resolution on organ donation and transplantation: national responsibility in meeting the needs of patients, guided by the WHO principles. *Transplantation* 2011 Jun 15;91 Suppl 11:S29–31.

WHO. WHO guiding principles on human cell, tissue and organ transplantation. *Transplantation* 2010 Aug 15;90(3):229–33.

Legislation and regulatory frameworks

The legislation listed below can be viewed online on the Australian Legal Information Institute website — www.austlii.edu.au.

Organ and tissue donation and transplantation

- ACT *Transplantation and Anatomy Act 1978*
- NSW *Human Tissue Act 1983*
- NT *Transplantation and Anatomy Act*
- QLD *Transplantation and Anatomy Act 1979*
- SA *Transplantation and Anatomy Act 1983*
- TAS *Human Tissue Act 1985*
- VIC *Human Tissue Act 1982*
- WA *Human Tissue and Transplant Act 1982*
- NZ *Human Tissue Act 2008*

Discrimination

- ACT *Discrimination Act 1991*
- NSW *Anti-Discrimination Act 1977*
- NT *Anti-Discrimination Act 1996*
- QLD *Anti-Discrimination Act 1991*
- SA *Equal Opportunity Act 1984*
- TAS *Anti-Discrimination Act 1998*
- VIC *Equal Opportunity Act 1995*
- WA *Equal Opportunity Act 1984*

Human rights

- ACT *Human Rights Act 2004*
- VIC *Charter of Human Rights & Responsibilities Act 2006*
- NZ *Bill of Rights Act 1990*
- NZ *Human Rights Act 1993*

Guardianship

Australian guardianship law is the key regulatory mechanism for protecting the health of adults with disabilities and the elderly. Australia has eight different guardianship regimes, which vary widely in their forms of regulation.

- ACT *Guardianship and Management of Property Act 1991*
- NSW *Guardianship Act 1987*
- NT *Adult Guardianship Act 1988*
- QLD *Guardianship and Administration Act 2000*
- SA *Guardianship and Administration Act 1993*
- TAS *Guardianship and Administration Act 1995*
- VIC *Guardianship and Administration Act 1986*
- WA *Guardianship and Administration Act 1990*

Capacity of children to consent

Specific legislation regarding the capacity of children to consent to medical procedures exists in New South Wales and South Australia.

- NSW *Minors (Property and Contracts) Act 1970*
- SA *Consent to Medical Treatment and Palliative Care Act 1995*
- NZ *Care of Children Act 2004*

Communication

- NHMRC (2004) *Communicating with patients. Advice for medical practitioners*. Commonwealth of Australia.
- NHMRC (2004) *General guidelines for medical practitioners on providing information to patients*. Commonwealth of Australia.
- NHMRC (2006) *Making decisions about test and treatments: Principles for better communication between healthcare consumers and healthcare professionals*. Commonwealth of Australia.
- Australian Commission on Safety and Quality in Health Care (2014) *Health literacy: Taking action to improve safety and quality*. Sydney: ACSQHC.

Cultural awareness

- NHMRC (2006) *Cultural competency in health: A guide for policy, partnerships and participation*. Commonwealth of Australia.
- RACGP (2011) *Cultural awareness education and cultural safety training*. The RACGP National Faculty of Aboriginal and Torres Strait Islander Health. Melbourne: Royal Australian College of General Practitioners. www.racgp.org.au/yourracgp/faculties/aboriginal/guides/cultural-awareness
- OTA Aboriginal and Torres Strait Islander Resources. <http://www.donatelife.gov.au/aboriginal-and-torres-strait-islander-resources>

Interpreters

- Telephone Interpreting Service: Free interpreting services for non-English speaking Australian citizens and permanent residents communicating with general practitioners and medical specialists in private practice and their reception staff.
131 450
www.immi.gov.au/living-in-australia/help-with-english/help_with_translating/free-services.htm#b
- Doctors Priority Line: A free telephone interpreting service for general practitioners and specialists providing services that are claimable under Medicare, delivered in private practices and provided to non-English speakers who are Australian citizens or permanent residents. The Doctors Priority Line is available 24 hours a day, seven days a week.
- NSW Health Standards Procedures for Working with Health Care Interpreters PD2006_053.
www.health.nsw.gov.au/policies/pd/2006/PD2006_053.html

Monitoring of organ donation and transplantation activity

- Australia and New Zealand Organ Donation (ANZOD) Registry — www.anzdata.org.au/anzod/v1/indexanzod.html
- Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) — www.anzdata.org.au/v1/index.html
- Australia and New Zealand Liver Transplant Registry — www.anzltr.org/
- Australian and New Zealand Cardiothoracic Organ Transplant Registry — www.anzcotr.org.au/

Assistance with travel and accommodation

All Australian states and territories operate a Patient Assisted Travel Scheme. These schemes provide a subsidy to assist with travel, escort and accommodation expenses incurred when people who live in rural and remote areas travel over 100 kilometres to access specialised health care not available within a specified distance from their place of residence.

- NSW Isolated Patients Travel and Accommodation Assistance Scheme — <http://www.health.nsw.gov.au/transport/Pages/iptaas.aspx>
- Queensland Patient Travel Subsidy Scheme — www.health.qld.gov.au/ptss/
- Victorian Patient Transport Assistance Scheme — www.health.vic.gov.au/ruralhealth/patient-transport-assistance.htm
- South Australian Patient Assistance Transport Scheme — www.countryhealthsa.sa.gov.au/Services/PatientAssistanceTransportSchemePATS.aspx
- West Australian Patient Assisted Travel Scheme — www.wacountry.health.wa.gov.au/index.php?id=pats
- Northern Territory Patient Assistance Travel Scheme — www.health.nt.gov.au/library/scripts/objectifyMedia.aspx?file=pdf/24/70.pdf&siteID=1&str_title=Brochure%20Information%20for%20Patients.pdf
- Tasmanian Patient Travel Assistance Scheme — www.dhhs.tas.gov.au/hospital/ptas
- ACT Interstate Patient Travel Assistance Scheme — www.health.act.gov.au/consumer-information/interstate-patient-travel

C. Process report

Background

For the last 20 years, the Transplantation Society of Australia and New Zealand (TSANZ) has maintained clinical guidelines comprising eligibility criteria for organ transplantation and protocols for the allocation of organs. In 2011, funding provided by the Organ and Tissue Authority (OTA) enhanced the capacity of TSANZ to develop clinical guidelines for organ transplantation from deceased donors that aim to provide:

- uniform eligibility criteria to ensure that the process of listing potential recipients for organ transplantation is equitable and transparent
- uniform allocation protocols to ensure consistency in organ allocation across Australia.

Following a joint request from TSANZ and the OTA, the National Health and Medical Research Council (NHMRC) undertook the development of *Ethical guidelines for organ transplantation from deceased donors* (the Ethical Guidelines). The development of the Ethical Guidelines was managed by the Office of NHMRC (ONHMRC) and resourced primarily by OTA under a Memorandum of Understanding between OTA and NHMRC.

In addition to setting the framework for ethical practice in relation to organ transplantation from deceased donors, the Ethical Guidelines are intended to inform the TSANZ *Clinical Guidelines for Organ Transplantation from Deceased Donors* that guide national clinical practice.

The development of the Ethical Guidelines was overseen by the Australian Health Ethics Committee (AHEC) with advice from an expert advisory group established under Section 39 of the *National Health and Medical Research Council Act 1992* (NHMRC Act).

Expert Advisory Group

Following provision of nominations from relevant organisations and consultation with OTA regarding final membership, NHMRC formally established the Expert Advisory Group (EAG) and members were appointed on 18 November 2013.

The EAG was chaired by a member of AHEC and included members with relevant knowledge and expertise in transplantation medicine, ethics and consumer issues.

The terms of reference for the EAG and details of its membership are provided in Appendix A.

Disclosure of interest and management of conflicts of interest

A robust and transparent system was used for disclosure of interest and management of conflicts of interest throughout the development of the Ethical Guidelines, in accordance with the requirements of the NHMRC Act and NHMRC's *Policy on the disclosure of interests requirements for prospective and appointed NHMRC committee members*.

Members of the EAG were required to disclose their interests before appointment as part of the process of the establishment of a NHMRC committee. Throughout the development of the Ethical Guidelines, members were required to disclose any changes to their interests. Consideration of disclosures of interests was a standing agenda item at every EAG meeting. The process involved members considering all disclosed interests and agreeing to a management strategy for any interest that was identified as being a real or perceived conflict of interest. There were no instances in the development process where an interest was identified as a perceived or real conflict of interest that required a management strategy.

A record of interests was managed by ONHMRC and relevant information was made publicly available on the NHMRC website to ensure transparency.

Consumer representation

Consumer representation was included in the membership of the EAG that developed the Ethical Guidelines (three members) and membership of AHEC that oversaw the development of the Ethical Guidelines (one member). Consumer engagement was a fundamental part of the public consultation process. The process also included consultation with NHMRC's Community and Consumer Advisory Group.

Other contributors

NHMRC project team

- Ms Jillian Barr
- Ms Mary Bate

Technical writer

- Ms Jenny Ramson, Ampersand Health Science Writing.

Development

The EAG met formally on four occasions from 13 March 2014 to 2 September 2014 in face-to-face meetings and via teleconference to develop the draft Ethical Guidelines for public consultation. The process also involved discussions with individual members of the EAG regarding specific issues. ONHMRC also sought advice from relevant members via email and telephone consultation on issues related to specific organ areas.

The draft Ethical Guidelines were submitted to AHEC for consideration at its meeting on 22 October 2014 and recommended for public consultation with some minor revisions. At its meeting on 27 November 2014, the Council of NHMRC advised NHMRC's Chief Executive Officer to release the draft Ethical Guidelines for public consultation.

Public consultation

Public consultation on the draft Ethical Guidelines was conducted in accordance with the NHMRC Act. Consultation was undertaken for the period 16 January 2015 to 6 March 2015. Eighteen submissions were received from a range of individuals and organisations. Copies of all submissions were provided to the EAG and AHEC. Submissions that were marked as not-confidential were published on the NHMRC website.

Finalisation and endorsement

The EAG met formally on four occasions from 10 April 2015 to 4 November 2015 to review and consider the comments received during the public consultation period. The EAG gave due regard to all submissions, systematically reviewing and discussing each one, with a consensus reached in each case on incorporating the suggestions made.

The Ethical Guidelines were considered by AHEC on 3 December 2015 and the Council of NHMRC on 10 March 2016. Finalisation of the document involved input from NHMRC's Principal Committee Indigenous Caucus. The Ethical Guidelines were formally endorsed by OTA and TSANZ in March 2016. It is anticipated that the document will be assessed for review in five years.

Acronyms and abbreviations

ANZCOTR	Australian and New Zealand Cardiothoracic Organ Transplant Registry
ANZDATA	Australia and New Zealand Dialysis and Transplant Registry
ANZLTR	Australia and New Zealand Liver Transplant Registry
ANZOD	Australia and New Zealand Organ Donation Registry
NHMRC	National Health and Medical Research Council
NPTR	National Pancreas Transplant Registry
ONHMRC	Office of the National Health and Medical Research Council
OTA	Organ and Tissue Authority
TSANZ	Transplantation Society of Australia and New Zealand
UN	United Nations
WHO	World Health Organization

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