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Australian Government
National Health and Medical Research Council

ORGAN AND TISSUE DONATION AFTER DEATH, FOR TRANSPLANTATION

GUIDELINES FOR ETHICAL PRACTICE FOR HEALTH PROFESSIONALS

WORKING TO BUILD A HEALTHY AUSTRALIA

Australian Government

National Health and Medical Research Council

ORGAN AND TISSUE DONATION AFTER DEATH, FOR TRANSPLANTATION

GUIDELINES FOR ETHICAL PRACTICE FOR HEALTH PROFESSIONALS

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INTRODUCTION

Organ transplantation is an effective treatment for many patients facing severe debility or premature death due to organ failure. Heart, lung, liver, kidney and pancreas transplants are well-established procedures in Australia. Tissue transplantation continues to develop rapidly, and transplants of eye tissue, heart valves, skin and musculoskeletal tissue are effective and well-established therapies.

Rates of transplantation are limited by the availability of organs and tissues. Recent changes to the Australian Organ Donor Register are intended to enable the wishes of the deceased to be carried out, with the aim of increasing the number of individual donors in Australia.

In light of changes to the Australian Organ Donor Register, the Australian Health Ministers' Advisory Council requested that the National Health and Medical Research Council (NHMRC) undertake a review of it's *Recommendations for the Donation of Cadaveric Organs and Tissues for Transplantation* (1996). In undertaking this task, the Working Party appointed by the Australian Health Ethics Committee (AHEC) (see Appendices A and B) also reviewed four discussion papers released by AHEC in 1997. Submissions from targeted consultations carried out in 2002 and 2005 were also considered.

SCOPE OF THE GUIDELINES

These guidelines update and collate material from all of the reviewed documents. They outline ethical principles for health professionals involved in donation after death and provide guidance on how these principles can be put into practice.

The scope of the guidelines can be defined as follows:

a) The task conferred on the Working Party was to provide ethical guidelines for those who facilitate and conduct organ and tissue donation for transplantation. AHEC does not have a role in actively promoting organ and tissue donation in Australia. Consequently, these guidelines;

- address transplantation and recipient issues only where they have implications for the ethical practice of organ and tissue donation;
- do not discuss mechanisms for promoting organ and tissue donation; and
- do not attempt to resolve differences in rates of organ and tissue donation and transplantation between population groups.

The Working Party recognises the need for further research into why donation and transplantation rates are particularly low among Aboriginal and Torres Strait Islander peoples and other culturally and linguistically diverse communities.

b) AHEC acknowledges that many different professionals and organisations are involved in organ and tissue donation; however, these ethical guidelines are aimed principally towards health professionals working in hospitals.

c) AHEC recognises that processes for donation and transplantation differ:

- between institutions;
- according to whether or not the donor dies in hospital; and
- according to whether organs or tissues are being retrieved.

The guidelines cannot give ethical advice specific to different circumstances, but aim to provide principles that can be applied in a variety of situations.

d) Legal requirements for many aspects of organ and tissue donation vary between jurisdictions. Health professionals are required to follow the legislation of the State or Territory in which they practise. Links to relevant legislation in each State and Territory are given in Appendix D.

e) As dictated by the terms of reference, the guidelines focus on organ and tissue donation for transplantation, and not for commercialisation of products developed from human tissues (tissue commercialisation is discussed in Appendix C).

In addition, the guidelines do not deal with:

a) ethical issues involved in the donation of organs and tissues by living donors (separate guidelines have been developed on this topic); or

b) stem cell research, xenotransplantation or the donation of sperm, ova or fetal tissue (these are addressed elsewhere — see Appendix D).

c) the donation of human organs or tissues for research purposes — the NHMRC National Statement on Ethical Conduct of Human Research contains ethical guidelines on the use of human tissue in research including consent to the use of the tissue.

STRUCTURE OF THE GUIDELINES

The advice in this document is based on a set of principles that guide ethical practice. The following chapters of the guidelines discuss:

a) rates of organ and tissue donation and transplantation and recent changes to the Australian Organ Donation Register (Chapter 1);

b) essential considerations for supporting ethical practice, including recognising the contribution of donor families, sensitivity to cultural and spiritual issues and respect for the beliefs and needs of staff members (Chapter 2);

c) the process of organ and tissue donation from the health professional's perspective, including practical application of the advice given in the previous chapter (Chapter 3);

d) ways in which institutions can support ethical practice in this area (Chapter 4).

As well as information about the development of the guidelines (Appendices A and E), the appendices include discussion of issues for further community consideration (Appendix C) and key information sources (Appendix D).

A booklet for the community and for family members of potential donors has been developed from these guidelines.

ORGAN AND TISSUE DONATION — PRINCIPLES

Donation of organs and tissues makes available a relatively scarce resource that has the potential to improve the health and life of recipients. Organs and tissues are given by donors and their families without expectation of reward or even acknowledgement by those who benefit. Altruism is a universal human virtue that is extolled as part of our Australian culture.

Donation is usually possible only because of the death of an individual, often in a sudden and unexpected manner. Affected families are likely to be exposed to significant stress at such a time. Much information needs to be passed on to family members and understood in a short period. Prior discussion and a known decision by the deceased about donation of organs and tissues are of major assistance.

Arrangements for retrieval of organs and tissues should be handled with great care and sensitivity. Whether or not the wishes of the deceased are known, everyone involved needs to recognise the distress and potential difficulties faced by most families.

These guidelines outline ethical standards for the process of donation and their implications for clinical and institutional practice, based on the following principles.

Principles embodied in these guidelines

a) Donation of organs and tissues is an act of altruism and human solidarity that potentially benefits those in medical need and society as a whole.

b) Organs and tissues for transplantation should be obtained in ways that:

- demonstrate respect for all aspects of human dignity, including the worth, welfare, rights, beliefs, perceptions, customs and cultural heritage of all involved;
- respect the wishes, where known, of the deceased;
- give precedence to the needs of the potential donor and the family over the interests of organ procurement;
- as far as possible, protect recipients from harm; and
- recognise the needs of all those directly involved, including the donor, recipient, families, carers, friends and health professionals.

c) Organs and tissues should be allocated according to just and transparent processes.

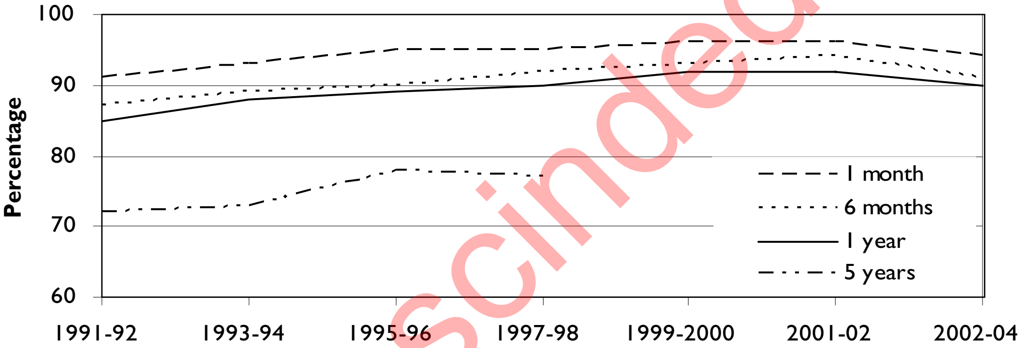
d) The choice not to donate should be respected and the family shown understanding for the decision.

1 BACKGROUND

1.1 DONATION AND TRANSPLANTATION FROM DECEASED DONORS

The transplantation of organs from deceased donors is well-established in Australia, with kidney transplants available since the early 1960s and heart, lung, heart-lung and liver transplants performed since the mid 1980s. Transplantation of pancreases and of pancreatic islets have also been performed. Australia's organ transplant success rates are high, with one-year survival rates for most organs above 80% (ANZOD 2005).

Figure 1.1 Graft survival following deceased donor kidney transplant, Australia 1991 to 2004



Source: ANZDATA Registry (2005)

Transplantation of donated tissues has a longer history than that of donated organs. The first corneal transplant was performed in Australia in 1941. The demand for donor corneas to restore sight continues to grow, particularly with improvements in surgical technique.

Transplantation of heart valves and bone grafts has been available since the mid 1980s. Transplantation of heart valves has become a preferred procedure for some major valve disorders of the heart and can prevent people from having to take anti-coagulant therapy for life. Bone grafts from deceased donors are transplanted for a number of purposes, sometimes as an alternative to amputation.

Eye and tissue banks for processing, storing and distributing tissues have been established to serve the growing need for tissues for transplantation.

An increasing range of deceased donor organ and tissue transplants is being performed overseas and likely to be introduced in Australia in the near future. These include small bowel transplants, which can be performed alone, combined with a liver transplant, or performed as a multivisceral transplant (multiple intra-abdominal organs). The emerging issue of novel therapies such as composite tissue allotransplantation (eg larynx, tongue) is discussed in Appendix C.

RATES OF DONATION

In 2005, there were 204 deceased organ donors with an average of 3.6 organ recipients per donor (ANZOD 2006). Donations from these solid organ donors included 161 corneas, 34 heart valves and ten bone donations which were sent to tissue banks. Data from the Australasian Tissue Banking Forum show that in 2005 there were 179 tissue donations — including skin and musculoskeletal tissue, heart valves and related tissue — from deceased donors (ATBF 2006).

Compared with other countries, Australia's 2005 organ donor rate of 10 per million population (the number of people who die and become donors out of the live population) is low and donation rates vary considerably between the states and territories. Australia's current rate is comparable to that in the UK, but much lower than the United States. Low donation rates are discussed briefly in Appendix C.

Most organ donors in Australia are Caucasian (192 of the 204 donors in 2006), with only small numbers of donors of Aboriginal, Torres Strait Islander or other non-Caucasian heritage (ANZOD 2006).

There is no upper or lower age limit to donation. The mean age of donors in 2005 was 42.8 years, with an age range of 0.6–79.5 years (ANZOD 2006).

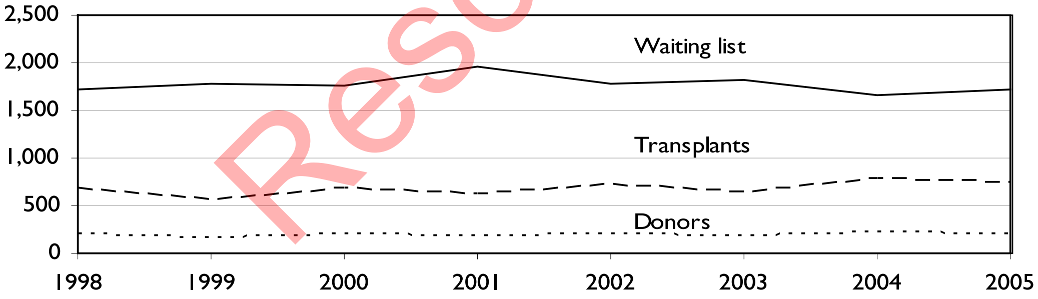
AVAILABILITY AND NEED FOR ORGANS

Few people die in circumstances that allow them to become organ donors. Organ donation is usually only possible in cases where a patient in an intensive care unit dies due to irreversible cessation of all brain function, while their heart and lung function is being maintained artificially. Organ donation following death determined by irreversible cessation of circulation (also known as non-heart beating donation) was the predominant source of organs before the brain function criterion for the certification of death was developed in the 1970s. Though the process has developed since then, this type of donation is re-emerging in several countries, together with standards to ensure that ethical practice is supported and acceptance of organ donation maintained among health professionals and the community (ACCCM & SCCM 2001; Bell 2003; British Transplantation Society 2003; Snell et al 2004; Bos 2005).[1]

Currently in Australia, stroke is the main cause of death in those who become multi-organ donors. Other common causes of death where organ donation may be a possibility are road and other trauma. These deaths are determined by irreversible cessation of all brain function. Until recently, only a very few donations of solid organs in Australia have been from people whose death was determined upon irreversible cessation of circulation, but numbers are now increasing (ANZOD 2006) and this is likely to continue. Policies and guidelines are being developed for the Australian context.

The need for organs far outweighs their availability (see Figure 1.2). Significant numbers of people die while awaiting transplantation, as their disease progresses beyond the point at which transplantation is possible. Low rates of donation from people of Indigenous and culturally and linguistically diverse backgrounds also limit the possibilities of potential recipients from these backgrounds if they do not wish to accept organs from donors from outside their cultural group.[2]

Figure 1.2 **Numbers of deceased donors and solid organ transplants and patients on the waiting list, Australia, 1998–2005**



Notes: Solid organ recipients transplanted in Australia from donors from Australia or New Zealand.

Source ANZOD (2005).

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[1] Programs for retrieving organs (principally kidneys) from such donors exist in the Netherlands, Japan, parts of the United States and in some centres in the United Kingdom. The British Transplantation Society has recently released guidelines relating to such donations (see Bibliography).

[2] There are also lower rates of transplantation among some groups. For example Aboriginal and Torres Strait Islander peoples with end-stage renal disease receive transplants at approximately one-third the rate of non-Indigenous patients (Cass et al 2004; McDonald 2004), have a lower rate of acceptance onto the waiting list and a lower rate of moving from the list to transplantation than non-Indigenous Australians (Cass et al 2003; McDonald 2004)

AVAILABILITY AND NEED FOR TISSUES

Many more people die in a way that makes them suitable to be tissue donors, because tissues such as bone, skin and heart valves can be retrieved up to 24 hours after circulation has ceased and can be stored for several months or years. Eyes must be retrieved as soon as possible after death, as must pancreatic islets, which rapidly deteriorate in the circumstances of warm ischaemia.

There is insufficient tissue donated to meet demand. This is because:

a) the applications of tissue transplantation are growing rapidly with innovations in tissue processing and surgery; and

b) donated tissues may not be suitable for transplantation.

1.2 RECENT DEVELOPMENTS IN THE AUSTRALIAN ORGAN DONOR REGISTER

During 2004, Australian Health Ministers reviewed the system of donation in Australia. A public statement was released announcing that all Health Ministers had agreed to new arrangements to help ensure that people who register to donate their organs and tissues after death have their wishes respected, while offering assurance that families will continue to be consulted at the time a donation is actually contemplated. State and Territory Health Ministers agreed to introduce clinical guidelines so that, upon a death in which organ donation is feasible, the Australian Organ Donor Register will be routinely consulted. Their stated aim was to ensure that the known wishes of the deceased, whether consenting or objecting, were respected and followed. Health Ministers encouraged Australians to talk to their families before recording their consent or objection to donation on the Register, because research shows that families are more likely to support organ and tissue donation if potential donors have discussed their wishes. The Recommendations of the Australian Health Ministers' Advisory Council Organ Donation Working Group are given in Appendix B.

One of the major recommendations of the review involved significant changes to the Australian Organ Donor Register, originally established in 2000. On 1 July 2005 the Register was instituted as the single national register of organ and tissue donors, changing from a register of intent to donate to one of consent or objection. The Register is administered by Medicare Australia (formerly the Health Insurance Commission) on behalf of the Australian Government.

Information recorded on the Register can be accessed via a secure Internet site by authorised personnel nominated by each jurisdiction, who have signed confidentiality agreements covering the access and use of personal information.

Around 801,000 Australians have registered their consent to donation on the AODR (Medicare Australia data as at 31 July 2006). There was a slight increase in registrations between 2004 and 2005 and a significant increase in family members requesting donation (32% compared with 20%) (ANZOD 2006).

There are some controversial issues associated with organ and tissue donation, such as:

a) systems aiming to increase rates of organ and tissue donation (eg an "opt out" system);

b) direct contact between donor families and recipients;

c) novel therapies (eg transplantation of limbs and faces);

d) directed donation of deceased donor organs; and

e) tissues and commercialisation of products developed from human tissues.

These are briefly discussed in Appendix C, with the aim of fostering and assisting community debate.

2 ETHICAL PRACTICE

This chapter outlines ethical considerations based on the principles given on page 5. Ethical practice in donation involves respecting the wishes of the deceased person, where these are known, and also recognising the needs of the bereaved family and carers. This involves:

a) being sensitive to cultural and spiritual differences that may affect decision-making (Section 2.1);

b) providing information relevant to the particular situation (Section 2.2);

c) offering bereavement counselling both at the time of death and later (Section 2.3); and

d) maintaining the confidentiality of both donor and recipient (Section 2.4).

It is also important to meet the needs and respect the beliefs of staff members (Section 2.5).

FURTHER INFORMATION

Resources that may assist health professionals in communicating with the family include:

a) *Making a Decision about Organ and Tissue Donation after Death* — the booklet for the community and for family members derived from these guidelines;

b) NHMRC guidelines on providing information to patients and on communicating with patients (see Appendix D); and

c) resources for health professionals on culturally competent practice (see Appendix D).

LEGAL GUIDANCE

Legal requirements concerning confidentiality vary between jurisdictions. Health professionals are required to follow the legislation of the State or Territory in which they practise. Links to relevant legislation in each State and Territory are given in Appendix D.

Checklist for ethical practice

Respecting individual and cultural differences

- Inform patients and families of the possibilities presented by organ donation and transplantation in a respectful and non-coercive fashion.
- Respect individual and cultural differences in the acceptance of organ and tissue donation and transplantation.
- When discussing death, be aware that there may be cultural and spiritual differences that affect acceptance that death has occurred following irreversible loss of all brain function

Providing information to families

- Provide information that is appropriate to the family's understanding and experience, at a pace determined by their needs and the particular situation.
- Provide information in a sympathetic environment, using simple language, avoiding the use of clinical terms and allowing time for questions.
- Ensure that health professionals who act as the main contact with families have specific training or significant experience in this area.
- Involve Aboriginal Health Workers or Aboriginal Hospital Liaison Officers when communicating with Aboriginal and Torres Strait Islander peoples.
- Use culturally appropriate materials and the services of trained interpreters when providing information to people from culturally and linguistically diverse backgrounds.

Providing ongoing care for families

- Offer ongoing bereavement counselling to meet the family's long-term as well as immediate needs in managing grief and addressing concerns or questions that may arise.

Ensuring confidentiality

- Maintain high levels of confidentiality for both donors and recipients.
- Refer media requests for information about donors or recipients in your care to the hospital public relations area.

Preserving well-being of health professionals

- Seek assistance through your institution (eg counselling, de-briefing) after difficult and stressful situations.
- Respect the beliefs of other staff members even if they differ from your own.

2.1 RESPECTING INDIVIDUAL AND CULTURAL DIFFERENCES

A fundamental ethical principle of donation is respect for the rights, beliefs, perceptions and cultural heritage of all those involved. Health professionals working in the area of donation are ethically obliged to:

a) consider and respect the views of families considering organ and tissue donation, whatever their basis; and

b) fully inform families and carers of the possibilities presented by organ and tissue donation and transplantation, acknowledging that the ultimate decision rests with individuals.

Even with full medical information, cultural and spiritual differences may affect acceptance of organ or tissue donation and that death has occurred when there is irreversible loss of all brain function. Any family member who is unsure of his or her religion's views on these matters may wish to consult a religious or spiritual adviser.

THE CONCEPT OF DONATION

For family and friends, the death of a loved one is usually a very difficult time. If the death is sudden and unexpected, affected families may be exposed to significant stress. This needs to be taken into account when providing information about organ and tissue donation and discussing consent and related issues. The following should be considered:

a) people may react very differently in emotionally charged situations;

b) differences in culture, experience and beliefs may have an impact on the way in which information is received and decisions are made;

c) death carries cultural and spiritual connotations that may differ between individuals and groups; and

d) family structures may need to be taken into account (eg elders or other authority figures).

Donation is a complex area and people's beliefs cannot be assumed. For example, organ and tissue donation and transplantation may be incompatible with the traditional beliefs of some Aboriginal and Torres Strait Islander people or with Shinto beliefs held by some Japanese people. However, whether such beliefs are held or not, health professionals are ethically obliged to inform all those involved of the possibilities presented by organ donation and transplantation. All members of the community should be given advice in a respectful and non-coercive fashion. Meeting people's information needs in a culturally appropriate way is particularly important (see Section 2.2).

Decision-making in organ and tissue donation has specific requirements and is discussed in detail in Section 3.1.

THE CONCEPT OF BRAIN DEATH

When discussing death, health professionals need to be aware that a person's understanding may reflect lack of information about the medical reality that has occurred, but there may also be cultural and spiritual differences that affect acceptance of the concept of the brain function criterion for determining death. Underlying the spiritual differences is a wide range of factors, including distinct notions about the meaning of death.

A widely accepted view emphasises the unity of mind and body in the living human being. From this viewpoint, the death of a person is understood to consist of the irreversible loss of the integrated and coordinated life of the person as a single living organism. When this functional unity is lost irreversibly, the person has died, even if 'life' continues at the sub-personal level of cells, individual organs or isolated physiological systems. A body that lacks all function of the brain lacks this intrinsic unified organisation, even though it may retain some degree of organisation due to the maintenance of some functions by technological means.

Many religious views generally accept this belief, seeing the person as an embodied spirit. Loss of integration can then be accepted as reflecting a loss of the presence of a soul. However, there is a range of beliefs around when the point of death is reached. Some argue that there remains sufficient integration of the body in a person with supported cardiac and respiratory function to constitute life even after the brain has ceased all function. Others believe that death has occurred when there is permanent loss of consciousness and loss of the capacity for spontaneous respiration. People who hold this view feel that brain death has occurred at this point, even though some functions of the brain (other than consciousness) are retained.

The removal of organs for transplant purposes should not take place if members of the family indicate that they believe that the patient may still be alive.

2.2 PROVIDING INFORMATION TO THE FAMILY

Families have a right to information that is relevant to their circumstances, given in a manner that is appropriate to their understanding and experience.

Families will differ in the amount of information and support they require. The pace of information provision should be determined by each family's needs and the particular situation.

The family and other significant members of the person's social network must receive and understand much information in a short and usually very stressful period of time. Health professionals need to:

a) explain death and how it is determined (see Sections 3.1 and 3.2);

b) outline the role of the next of kin in deciding whether to agree to fulfil the deceased's previously expressed wishes to donate organs or tissues or, if the deceased's wishes were not known, making a decision about donation (see Section 3.3);

c) describe what will happen and why if donation is to proceed (see Sections 3.4 and 3.5); and

d) explain processes for ongoing support of the family, including counselling.

Where possible, one health professional should be the main contact for the family throughout this process. Health professionals who have significant experience in this area, or who have undergone special training (and may be known as trained requesters) are best qualified to support the family. There is a range of training programs available that relate to the process of donation, including grief counselling and ways to approach families about donation (see Appendix D). Such training will assist health professionals to deal sensitively with the family, and have a clear understanding of donation. The assistance of a social worker, senior nurse, religious advisor, family doctor, psychiatrist, psychologist or a combination of people with separate special skills, should also be available.

Families should be given the opportunity to ask relevant questions and to have their questions answered in a sympathetic environment. Information needs to be provided in a manner that is suitable to their understanding and reinforced with written materials. Language that is simple and free of clinical terms will help to ensure that the information is understood and retained (NHMRC 2004). Independent interpreters (preferably trained as outlined above), culturally appropriate materials and consent forms should be available for people from culturally and linguistically diverse backgrounds. Where this is not possible, telephone interpreter agencies can provide relevant services.

For Aboriginal and Torres Strait Islander families, the involvement of an Aboriginal Hospital Liaison Officer and/or Aboriginal Health Worker will help to ensure that communication takes place in a culturally appropriate way.

2.3 PROVIDING ONGOING CARE FOR THE FAMILY

Care for the family does not stop with the death of the patient and, if donation is to proceed, retrieval of organs and tissues. The same health professionals who supported the family up to this stage should continue to be available to them, along with ongoing support services if desired.

Bereavement services, operated by qualified staff, can assist families in managing grief and addressing any concerns or questions that may arise as time goes on. These services, offered at the time of the death and immediately afterwards, should continue to be available to meet the family's long-term as well as immediate needs. Where children are directly affected, referral to a counsellor specialising in the care of children may be advisable.

Where donation has taken place, it is established practice for the donor coordinator to send a letter of thanks to the donor's family. This letter also offers follow-up support.

Where possible, the family should be given the opportunity for further discussion with the consultant doctor and other members of the intensive care team at a later date.

2.4 ENSURING CONFIDENTIALITY

Identifying information about the deceased, the use of retrieved organs and tissues and information about recipients, are subject to the normal ethical obligations of confidentiality. Statutory rules about disclosure apply in all States and Territories (see Appendix D).

Difficulties with confidentiality may arise in clinical units that care for both the donor and recipient, and in smaller health services. All staff should be aware of the need for confidentiality, and the importance of individual sensitivity and vigilance in this regard. It is preferable for approaches by the media to be handled by the hospital public relations staff rather than by individual health professionals.

In some situations, the next of kin may wish to know when the transplant occurs and some basic information about the recipients. Similarly, the recipient may wish to write an anonymous letter of thanks to the donor family. Such letters may be forwarded via the donor coordinator or the person who sought agreement for the donation. Thanksgiving services provide a common venue for donor families and recipients, but caution may be necessary to avoid the risk of breaching confidentiality. Health professionals have a responsibility (and legal obligation) to maintain the confidentiality of both donors and recipients.

Discussion of potential mechanisms to support contact between donor families and recipients is included in Appendix C.

2.5 PRESERVING WELL-BEING OF HEALTH PROFESSIONALS

A range of health professionals is likely to be involved in the process of determination of death, organ and tissue retrieval and transplantation. These professionals are obliged to preserve their own well-being and to pay attention to the impact of these events on their colleagues.

The process of determination of death, organ and tissue retrieval and care of the donor's family is intense and may cause personal stress to the health professionals involved. Institutional support for staff members involved in determination of death and donation is discussed in Section 4.3.

SUPPORTING HEALTH PROFESSIONALS

The following points give suggestions for maintaining personal well-being and supporting fellow staff members.

a) A supportive work environment that recognises and validates responses to difficult and stressful situations will facilitate recovery. Health professionals whose wellbeing is affected after involvement in the process of determination of death and organ and tissue donation should seek assistance (eg counselling, debriefing) through their institution.

b) Health professionals should have access to resources and training that will enable them to support donor families.

c) Health professionals who do not accept that death has occurred when there is irreversible cessation of all brain function should notify their institution of this. These views should be respected and those holding these views not be required to participate.

d) Health professionals should notify their institutions if they object to undertaking non-therapeutic procedures on patients prior to death in order to facilitate organ procurement after death.

e) While an individual health professional should not be required to participate in an activity that the person believes to be wrong, the exercise of conscientious objection should never put a patient receiving care at risk of harm.

f) A person who exercises conscientious objection to participate in an activity ought not to undertake activities within the institution or directly involving the institution that might undermine confidence in others who have chosen to participate in organ and tissue donation and transplantation.

g) Health professionals involved in the retrieval of organs and tissues should be mindful of the relationship that may have developed between staff members caring for the deceased and the deceased's family.

h) Members of the retrieval team should be aware of the potential impact of organ and tissue donation and removal of organs and tissues on the staff and resources of the hospital that cared for the deceased patient, and seek to minimise any disruption and inconvenience to them.

i) Following transplantation of organs and tissues, members of the retrieval team may wish to communicate through the state donor agency with relevant staff in the donor hospital, thanking them for their care of the donor and informing them of the outcome of the transplantation to their recipients.

3 IMPLICATIONS FOR CLINICAL PRACTICE

This chapter outlines the implications for clinical practice resulting from the ethical considerations outlined in Chapter 2.

Before organ and tissue procurement can proceed:

a) death is determined on the basis of either irreversible loss of all brain function (Section 3.1), or of cessation of circulation that is irreversible without unduly burdensome intervention (Section 3.2);

b) appropriate procedures are carried out for providing information and seeking consent, including consulting the Australian Organ Donor Register (AODR) and involving the next of kin and others who are close to the patient (Section 3.3);

c) suitability for organ and tissue donation is determined (section 3.4); and

d) the designated officer (whose role is to ensure that the process follows institutional protocol) gives authorisation (see Chapter 4).

The patient and his or her family are treated with respect and dignity throughout the process (Section 3.5).

Ethical, clinical and legal practice requires the provision of certain information and services to the patient's family as well as their involvement in the consent process. Information that relates to caring for the patient's family is given in shaded boxes.

USE OF TERMINOLOGY IN THESE GUIDELINES

Death can be determined in two ways — after the irreversible loss of all brain function or the irreversible cessation of circulation. Tissue or organ donation may be possible after death has occurred, determined by either of these methods.

Death determined by the irreversible loss of all brain function — means that the nature of the brain injury is such that all function of the brain has ceased and the loss of function is permanent. Factors that may temporarily suppress brain function are excluded and the nature of the injury is known and likely to have led to loss of brain function. Clinical tests confirm that the extent of the injury includes loss of brain stem activity. Ancillary tests may be done to confirm absence of blood flow to the brain.

Death determined by irreversible cessation of circulation — irreversible means:

a) sufficient time has elapsed to eliminate the possibility of auto-resuscitation so that, in the absence of resuscitative attempts, cessation is irreversible;

b) resuscitative attempts are either contraindicated on medical grounds, given the progressive nature of the condition, or the patient (or the person with legal authority to make his or her medical decisions) would consider resuscitative measures to be unduly burdensome.

CLINICAL GUIDANCE

Clinical guidelines that are relevant to organ and tissue donation have been developed by a number of organisations — the Australian and New Zealand Intensive Care Society (ANZICS), the Transplantation Society of Australia and New Zealand (TSANZ), the Australasian Transplant Coordinators' Association (ATCA), the Australasian Tissue Banking Forum (ATBF) and the Eye Banks Association of Australia and New Zealand (EBANZ). These are listed in Appendix D. Health professionals should consult these guidelines as well as following institutional protocols.

LEGAL GUIDANCE

Legal requirements concerning determination of brain death, antemortem interventions and consent procedures vary between jurisdictions. Health professionals are required to follow the legislation of the State or Territory in which they are practising. Links to relevant legislation in each State and Territory are given in Appendix D.

Checklist for ethical practice

General principles

- Follow standards for best practice (in line with national guidelines and local protocols) in the care of patients who may become donors.
- Determine and confirm death using established criteria and guidelines.
- If involved in the care of a potential recipient (where this is known), do not participate in decision-making about the care of patients who may become donors or in the determination of their death.
- Ensure that procedures for informing and seeking consent are properly followed, including involving patients/families and meeting legal requirements.

Death determined by irreversible loss of all brain function

- Assist the patient's family to understand testing with reference to the brain function criterion and the significance of confirmation of irreversible loss of all brain function.
- If initial tests indicate irreversible loss of all brain function, establish the patient's wishes concerning organ and tissue donation by consulting the AODR and the family.

Death determined by irreversible cessation of circulation

- When the death of the patient is imminent and inevitable, assist the patient's family in decision-making about discontinuing treatment.
- If a decision is made to discontinue treatment, establish the patient's wishes concerning organ and tissue donation by consulting the AODR and the family.
- Discuss organ and tissue donation after a decision is made to discontinue treatment. If the matter is raised by the family before this time, either defer discussion or refer the family to an experienced clinician who is not involved in management of the patient.

3.1 DONATION FOLLOWING DEATH DETERMINED BY IRREVERSIBLE LOSS OF ALL BRAIN FUNCTION

When irreversible loss of all function of the brain is indicated by the established criteria, the AODR and the patient's family should be consulted to determine the patient's wishes concerning organ and tissue donation.

DETERMINATION OF IRREVERSIBLE LOSS OF ALL BRAIN FUNCTION

Irreversible loss of all brain function is clinically confirmed by two experienced medical practitioners who examine the patient independently. In some cases, ancillary testing — angiography or radionucleotide imaging — is used to provide additional evidence of lack of blood circulation to the brain.

Caring for the patient's family during determination of death

If assessment to confirm loss of all brain function is planned, the patient's family should be advised that two sets of tests will take place and why they are considered necessary. If initial tests indicate irreversible loss of all brain function, family members should be told of these results and advised that they may be present for the second set of tests if they wish. If family members decide to attend the tests, counselling should be offered.

For some people, understanding death after loss of all brain function may be difficult. t is important that family members understand that the loss of all brain function is irreversible and the implications of this fact.

Actions that can be taken to assist the patient's family in their understanding include:

a) explaining the process of determining irreversible loss of all brain function, including discussion of:

  - the basis of the assessment (eg that the injury and the disease process are likely to have resulted in irreversible loss of all brain function);
  - ways in which other causes of coma (such as drugs or metabolic conditions) are ruled out before tests for loss of all brain function are carried out;
  - the legal requirement for specialists to be involved in performing these assessments and for the assessments to be conducted over a specified period;
  - the range of functions that are tested clinically;

b) explaining the difference between irreversible loss of all brain function and coma or post-coma unresponsiveness (previously known as vegetative state) and the ways in which these conditions are diagnosed and differentiated;

c) explaining any ancillary tests that are undertaken and providing visual images from these tests;

d) ensuring that terminology concerning death and its causes is clearly defined (see Glossary) and used consistently.

Specific concerns that family members may raise

a) *"The person does not 'look' dead"* — Despite irreversible loss of all brain function, respiration and circulation can be artificially maintained for prolonged periods of time in an intensive care unit. During this time, the deceased may seem alive in that they appear to be breathing and their blood is circulating.

b) *"The person might still recover"* — One of the earliest controversies surrounding the brain function criterion related to claims in the popular press that patients fulfilling the criterion were capable of complete recovery. However, there is no evidence of recovery in patients in whom the established criteria have been strictly applied. Where there is doubt or difficulty, ancillary testing may be used to confirm absence of blood flow to the brain.

c) *"The term "brain dead" is not clear"* — Patients who fulfil the criteria for irreversible loss of all brain function are commonly said to be "brain dead". This term is used incorrectly in other contexts to describe much lesser degrees of neurological dysfunction and even in colloquial language to describe someone who is feeling vague or has a hangover. (See the Glossary for suggested usage around determining death and its causes.)

ESTABLISHING CONSENT TO DONATION

If initial tests indicate irreversible loss of all brain function, the AODR should be consulted by an authorised health professional.[3] The patient's family should also be asked about organ and tissue donation as outlined in Section 3.3 — this includes taking all reasonable steps to determine if the patient had changed his or her mind since registering.

Discussion of organ and tissue donation

Organ and tissue donation should not be raised until clinical assessment has indicated irreversible loss of all brain function and the patient's family has been informed of these results and been given time to understand and accept the implications.

If a family member wishes to discuss organ and tissue donation before testing is completed, the approach should be acknowledged and documented. However, a decision about donation should be deferred until after death is certified.

ORGAN AND TISSUE RETRIEVAL

When death has been determined by irreversible loss of all brain function, the deceased may be suitable for donation of vascularised organs (kidneys, liver, heart, lungs, pancreas) and tissues (corneas, heart valves, skin, bone, musculoskeletal tissue). Additional management may be initiated after death has been determined, to monitor and maintain the condition of the organs and tissues until the time of retrieval.

Organ and tissue retrieval may proceed following determination of death by the brain function criterion only when:

a) appropriate consent has been given (see Section 3.3);

b) neither practitioner involved in testing for irreversible loss of all brain function is:

  — a member of the organ retrieval or transplant team; or

  — the practitioner caring for the potential recipient of the organ or tissue to be removed; or

  — the designated officer authorising the removal of organs or tissues; and

c) the designated officer has reviewed the whole process and ensured that it is in accordance with institutional protocol, the standards of the relevant professional bodies and the law, and has given written approval for the retrieval process to occur (See Chapter 4).

The family of the deceased should not incur any financial costs for management relating directly to organ and tissue donation.

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[3] Personnel authorised to access the AODR vary between jurisdictions and institutions.

FRAMEWORK FOR DONATION FOLLOWING DEATH DETERMINED BY IRREVERSIBLE LOSS OF ALL BRAIN FUNCTION*

Patient is on a ventilator following severe brain injury

↓ If signs suggest loss of all brain function

Time is allowed to assess nature and extent of injury and the possibility of recovery

↓ If signs suggest loss of all brain function

Other possible causes of lack of brain function investigated

↓ If no other causes found

First clinical tests to confirm loss of all brain function

↓ If tests find no brain activity

Patient's family advised of outcome of tests
(may choose to be present for second set of tests) (see page 24)

↓

Australian Organ Donor Register consulted and family informed of any registration
(see pages 32 to 33)

↓ If no known objection from patient

Second set of clinical tests to confirm loss of all brain function

↓ If tests confirm irrecersible loss of all brain function

Death certified and documentation completed

↓

Family asked for agreement to organ and/or tissue donation
(see pages 33 to 36)

↓ If agreement from next of kin

Designated officer reviews process (see page 42)

↓ If designated officer gives authority

Organs and/or tissues removed (see pages 25 and 38)

↓

Family may view body and arrange funeral (see page 39)

↓ If family wishes

Ongoing support provided to family (see page 18)

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* This framework is meant as a guide only. The actual sequence of events will depend on individual circumstances and local practice.

3.2 DONATION FOLLOWING DEATH DETERMINED BY IRREVERSIBLE CESSATION OF CIRCULATION

Determination of death by irreversible cessation of circulation is a legally and clinically accepted practice. Donation following death determined by irreversible cessation of circulation may involve consideration of ethical issues associated with discontinuation of treatment and the need to reduce warm ischaemic time and preserve organ quality.

Tissue donation following death determined by cessation of the circulation has been routine for decades. Organ donation in these circumstances is a practice that is re-emerging in Australia. For organs, this type of donation is only possible if death occurs in hospital, while tissue donation may be possible whether death occurs in the hospital setting or not. This is because:

a) organs are damaged by warm ischaemia — organ donation may be possible in controlled circumstances[4] when confirmation of irreversible cessation of circulation occurs as a predictable event following discontinuation of treatment; and

b) certain tissues do not require an intact cardiovascular system to be viable for transplantation — bone, skin, heart valves and corneas can be retrieved within 12–24 hours of death following irreversible cessation of circulation without the need for interventions to maintain tissue quality.

The need to reduce warm ischaemic time and preserve organ quality in patients who may become organ donors following death after irreversible cessation of circulation raises a number of ethical issues, including:

a) the possible need for the patient to undergo interventions before death that are of benefit to potential recipients but not to the patient (see below);

b) the potential for medical care of dying patients to be influenced by the need to retrieve organs as soon after death as possible in order to minimise warm ischaemic time; and

c) uncertainty about whether the patient will die within the timeframe that allows organs to be suitable for transplantation (although some tissues may still be donated).

Caring for the patient's family

The relative urgency in initiating perfusion and retrieval can complicate the process of providing information to the patient's family and carers and their decision-making. It is important that the family understands that the care of the patient is not compromised by the need to preserve organs and that counselling and support are provided.

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[4] The International Maastricht Conference on Donation After Cardiac Death has designated categories of donors following death after cessation of circulation, which are divided into controlled and uncontrolled circumstances. See Glossary for an outline of these categories.

DISCONTINUATION OF TREATMENT

Patients who have the potential to become organ donors following death determined by irreversible cessation of circulation are likely to be unconscious and may require high levels of medical support. Their wishes regarding organ donation may not be known. In some cases, patients admitted to the emergency department with catastrophic injuries are given ongoing treatment to allow time for assessment and for the family to be contacted. During that time it may also be possible to ascertain the wishes of the patient and the family about organ donation.

In all cases, it is imperative that the decision to discontinue treatment is independent of any consideration of donation.

Discontinuation of treatment may only be considered when:

a) the competent patient, the family or the legally appointed decision maker has agreed to discontinuation of burdensome treatment; and

b) treatment continues to maintain the patient's comfort and dignity.

If irreversible cessation of circulation does not occur within a reasonable time (as designated by institutional protocol) after treatment is discontinued , the patient is returned to a prearranged area for continuing care.

A collaborative approach

Families and health professionals have an obligation to work together to make compassionate and respectful decisions for patients who lack decision-making capacity, taking previously expressed patient wishes into account where known. To ensure that decisions are fairly made, the decision-making process and its outcomes should be clear to all those involved.

ESTABLISHING CONSENT TO DONATION

If a decision to discontinue treatment is made, the matter of organ donation after death can be raised. The following guidelines apply:

a) if the patient is competent, the patient should be consulted about his or her wishes concerning organ and tissue donation after death;

b) if the patient is not competent the AODR should be consulted by authorised personnel. The family should also be asked about organ and tissue donation as outlined in Section 3.3 — this includes taking all reasonable steps to determine if the patient had changed his or her mind since registering.

Discussion of organ and tissue donation

The option of organ and tissue donation may be raised with the patient's family only if they have come to a decision to discontinue treatment. If the matter is raised by the family before this time, the approach should be acknowledged and documented. However, the discussion should be deferred until a decision has been taken or referred to an experienced clinician who is not involved in management of the patient.

ANTEMORTEM INTERVENTIONS

In the circumstances defined below, interventions may be carried out before death with the aim of maintaining organ viability following irreversible cessation of circulation. Such interventions include:

a) administration of drugs that enhance organ quality (eg heparin);
b) moving the patient to the operating room before discontinuation of treatment so that organs and tissues may be obtained immediately after death; and
c) cannulation of femoral vessels, to facilitate infusion of preservation solutions once death has occurred.

Where the law permits, it is ethical to proceed with these interventions if:

a) there is evidence that the patient wanted to be a donor;
b) the patient or family have sufficient information to make informed decisions about antemortem interventions;
c) the patient, if competent, has given proper consent or, if the patient is not competent, the family gives permission based on there being reasonable grounds for believing that the patient would have consented;
d) interventions will not contribute to the cause of death or compromise the continuing care of the patient; and
e) measures are taken to prevent any associated pain or discomfort.

Costs for these interventions must not be charged to the family of the deceased.

Care of the patient's family if antemortem interventions take place

Family agreement to antemortem interventions should be based on there being reasonable grounds for believing that the patient, if competent, would have consented, or the patient, while competent, has already consented. There should be no known objection to donation by the patient.

Agreement for interventions before death should be documented. This is a separate process to agreement to organ and tissue donation, which is discussed in Section 3.3.

ORGAN AND TISSUE RETRIEVAL

When death has been determined by irreversible cessation of circulation, the deceased may donate vascularised organs (kidneys, liver, lungs, pancreas) and tissues (corneas, skin, heart valves, bone, musculoskeletal tissue).

Retrieval of organs and tissues may still take place without the antemortem interventions outlined above. In these cases it is particularly important that discontinuation of treatment takes place in the operating room to minimise warm ischaemic time. This process needs careful planning to accommodate the feelings of the family, carers, friends and health professionals.

Organ and tissue retrieval following determination of death by irreversible cessation of circulation may be considered only when:

a) death is determined by a doctor independent of the organ and tissue retrieval or transplant teams;

b) pulse and blood pressure monitoring take place throughout the process of dying and a record of the observations is kept with the patient's record;

c) once circulation ceases, sufficient time has elapsed to be certain that this is irreversible without intervention that is unduly burdensome;[5]

d) the designated officer has reviewed the process and ensured that it is in accordance with institutional protocol, the standards of the relevant professional bodies and the law, and has given written approval for retrieval (see Chapter 4).

The family of the deceased should not incur any financial costs for management relating directly to organ and tissue donation.

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[5] This time is allowed to exclude the possibility of auto-resuscitation and will vary depending on the cause of death, patient's age and comorbidities. Guidelines regarding the length of this interval have been developed in some countries (see Appendix D).

FRAMEWORK FOR DONATION FOLLOWING DEATH DETERMINED BY IRREVERSIBLE CESSATION OF CIRCULATION*

Patient unable to survive severe injuries or other illnesses without unduly burdensome treatment (see page 28)

↓

Consultation with family (see page 28)

↓ If treatment is to be discontinued

Australian Organ Donor Register consulted and family informed of any registration (see pages 28 to 33)

↓ If no objection

Family asked for agreement to organ and/or tissue donation (see pages 33 to 36)

↓ If agreement from next of kin

Unduly burdensome treatment discontinued# (see page 29)

↓ If circulation ceases within a reasonable time (as designated by institutional protocol)

Death certified and documentation completed (see page 36)

↓

Designated officer reviews process (see page 42)

↓ If designated officer gives authority

Organs and/or tissues removed (see pages 28 and 38)

↓

Family may view body and arrange funeral (see page 39)

↓ If family wishes

Ongoing support provided to family (see page 18)

* This framework is meant as a guide only. The actual sequence of events will depend on individual circumstances and local practice.

\# Where antemortem interventions are legally permissible, there is evidence that the patient, when competent, wanted to donate organs after death and the family has given informed agreement to the interventions, these take place before treatment is discontinued.

3.3 CONSENT TO DONATION

Retrieval of organs and tissues can proceed only when appropriate consent procedures and institutional protocols have been followed (see Chapter 4). Donation should be raised with the family by a health professional with experience or specific training in this area (sometimes known as a trained requester). In order to provide continuity of care for the family, it is preferable that this person is a health professional who has been in contact with the family throughout the process. Counselling and support for the family should be available before, during and after the decision to donate.

The consent procedures outlined in this section apply to the donation of organs and tissues by patients who die in hospital.[6] Legislation concerning procedures for consent to donation is specific to each jurisdiction, with variations in the definition of senior next of kin, the usual hierarchy of next of kin and whose wishes take priority, how the senior next of kin may be contacted and the role of the designated officer. Health professionals should be aware of legislative requirements in the State or Territory in which they practise (see Appendix D).

CONSULTING THE AODR

In all States and Territories, the AODR should be routinely consulted following the initial set of tests to determine death by the brain function criterion or following a decision to discontinue treatment in a patient whose death is imminent.

The function of registering is an active expression of consent or objection to donation should the circumstances of death allow it. Registration carries with it an expectation that this decision will be accessed at the appropriate time — if circumstances exist where donation may be possible — and will be conveyed to the family and complied with to the extent possible.

Deceased's wishes recorded

If the deceased person's consent or objection to donation after death is recorded in the AODR, then the senior available next of kin (with others who are close to the deceased) should be advised of this registration.

It is important to check whether the deceased had changed his or her intent since registering, especially if the time between registration and death is many years. The senior available next of kin should be consulted about:

a) whether the deceased had changed his or her decision; and

b) whether there are altered circumstances that the deceased would have wanted to have taken into account.

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[6] Consent to organ and tissue donation as discussed here does not include consent to commercialisation of products derived from human tissue. Emerging issues associated with commercialisation are discussed in Appendix C.

Deceased's consent not recorded

If the person's wishes are not recorded on the AODR, legislation and good practice require that the senior next of kin be asked to consider the issue and, if they agree, to provide consent for removal of organs or tissues. Consultation with others who were close to the deceased may also be appropriate. In cases where the patient's death is expected to occur after discontinuation of treatment, discussions with family members should be sensitive to their likely feelings, both in the circumstances and when they reflect back on how they were cared for.

In all cases, a written or other record of consent should be kept.

CONTACTING THE NEXT OF KIN

The way in which the senior next of kin is contacted about donation will vary according to jurisdictional requirements, the type of donation and circumstances (for example the senior next of kin may not be in the same place as the deceased). For organ donation, personal contact by a professional with relevant experience is preferable and may be a legal requirement. Telephone contact (which is the usual practice for tissue donation) is only appropriate if a reasonable interval has passed since the next of kin was informed of the death. The details of contact with the next of kin should be fully documented.

Contact should be mainly with the senior next of kin, however respect for cultural practices may require broader consultation, with the senior next of kin conveying or confirming the eventual decision.

Family consultation

Prior consent from the deceased person is sufficient to authorise donation. However, the deceased's family is also consulted and agreement sought. The recorded consent of the deceased informs and guides the process but good practice recognises the important role of relatives.

The senior available next of kin should be asked:

a) whether any family members, especially those present, are distressed by the prospect of organ or tissue retrieval;

b) whether the family is satisfied with the explanation offered that death has occurred;

c) which organs or tissues are to be taken and whether there are particular organs and tissues that they would prefer not to be taken; and

d) whether the organs and tissues are to be used for transplantation, research[7] or both.

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[7] Guidelines on the use of human tissue in research are given in the National Statement on Ethical Conduct in Research Involving Humans (see Appendix D).

There is thus a discussion and decision process to be engaged in with the senior available next of kin and involving others who were close to the deceased.

Prior consent by the deceased has ethical and emotional significance in that:

a) respecting the wishes of the deceased is usually important to the living;

b) the deceased's consent indicates approval of the practice of removing organs and tissues after death for transplantation;

c) the consent removes any notion of exploitation of the body of the deceased; and

d) the deceased's written consent carries legal significance in validating the removal of organs and tissues after death for medical purposes in the legislation of every State and Territory.

Next of kin unavailable

In some situations there may be no written or registered consent or objection and no next of kin (as defined in the legislation) who can be contacted within a timeframe that allows for organ or tissue donation. The designated officer has an important role in such situations to decide whether sufficient efforts have been made to contact the next of kin. In some jurisdictions, the designated officer may authorise organ and tissue procurement if there is satisfactory indication of the deceased's wishes to donate. This indication may come from members of the deceased's extended family or from friends with a demonstrable long-term relationship with the deceased, who are available and in agreement about the deceased's previously expressed wishes about organ and tissue donation.

FAMILY OBJECTIONS TO DONATION

Although most families agree to donation if the deceased person had registered consent,[8] in some circumstances family members may object and there may be potential for distress if organ and tissue donation proceeds. Families may need time to consider and discuss their views and recognise and resolve differences. If the objection is unlikely to be resolved or the prospect of organ and tissue donation is causing significant distress to close family members, the process of donation should be abandoned, despite the previous consent of the deceased. Consent is a permission not a directive. Discussions in these situations need to be handled with extreme care and sensitivity, and should be properly documented.

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[8] If the deceased person had consented to donation in life, legislation in all States and Territories does not require family consent or agreement. However, in order to ascertain whether the deceased had changed their intention, families should be consulted.

Supporting informed decision-making

Family members should be given adequate time, information and privacy to make a free and comprehending response to the request for donation, including the opportunity to consult people outside the hospital if they wish. All relevant information needs to be offered — it is not appropriate to withhold information because of its potential to cause distress to the relatives of the deceased.

Discussions need to be handled with both care and sensitivity and the difficulties of decision making acknowledged for families who may not know the wishes of the deceased. Any questions should be answered openly, honestly and with sensitivity. Support for family members should also be available from relevant hospital staff such as religious advisers, social workers and liaison psychiatrists, who have training in the care of newly bereaved people.

There may be next of kin who agree to donation, but do not wish to discuss the matter in detail. They should still be provided with written information on organ and tissue donation and advised that they may request further discussion in the future.

Information provided to families

Topics to be covered when organ and tissue donation is discussed with the family include:

a) the clinical actions and procedures that will follow;

b) whether there will be an autopsy or coronial involvement, consent procedures for these and details of how these will proceed;

c) in the case of patients whose death followed irreversible loss of all brain function, the fact that there may be some delay before organs and tissues are removed;

d) the procedure of retrieval for specific organs and tissues (including that the body will be treated with the respect due to all persons);

e) the opportunity to view the body after organ and/or tissue retrieval (in coronial cases this may only occur at a time and place dictated by coronial requirements);

f) the benefits and risks to recipients (eg the donation may save lives or improve quality of life, the graft or recipient may not survive);

g) the fact that donations are directed according to allocation criteria and families cannot impose conditions;

h) the general results of transplantation (eg graft and patient survival rates);

i) the need for blood sampling for either immediate or future testing for viral and other infections, blood group and HLA type;

j) results of blood sampling including the implications of a positive result for a virus;

k) the possibility that the patient may be unsuitable to donate due to medical or social risk factors (if the deceased is later found to be unsuitable for donation, the next of kin should be sensitively informed by the person who originally approached them about organ and tissue donation and offered counselling);

l) if the deceased is medically unsuitable for donation, that tissues may be used for research with appropriate consent

m) the fact that there are no charges for any tests or management associated with organ and tissue donation and retrieval (but that this does not include funeral costs);

Continued ➔

n) legislative protection of any information that would identify either donor or recipient (see below);

o) the availability of counselling services, whether the donation proceeds or not; and

p) the availability of support organisations (see Appendix D).

DOCUMENTING THE DECISION-MAKING PROCESS

A note should be made in the patient's medical record of discussions about donation with the family, regardless of whether donation ultimately takes place.

The next of kin's role in the decision-making process should also be documented (eg whether they agree to follow the patient's expressed wishes or agree to donation on the patient's behalf when these are not known). The organs and tissues to be donated should be specified as well as the intended use, whether for transplantation, other medical or scientific purposes, or both.[9]

The removal of lymph nodes and spleen for tissue typing purposes, and vessels for facilitating transplantation, should be specified. Blood being taken for blood typing, serology, cross-matching or perfusion into the recipient of an organ, should also be specified.

3.4 IDENTIFICATION AND SUITABILITY OF POTENTIAL DONORS

The process of determining suitability for organ and tissue donation should be initiated by medical or other appropriately qualified staff, depending on the circumstances. As outlined in Sections 3.1 and 3.2, this process includes consulting the Australian Organ Donor Register and contacting the deceased's next of kin to confirm consent. Local legislation and requirements for referral to the coroner must be met and established criteria for suitability followed.

TSANZ and ATBF have developed criteria for medical suitability of deceased donors. The criteria used to determine suitability for donation of organs and tissues include the following:

a) individual evaluation of each potential donor with a careful review of the history and a thorough clinical examination; and

b) a rigorous screening routine designed to discover the existence of malignancy and significant transmissible and other diseases.

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[9] In some States and Territories this may include research in projects approved by relevant Human Research Ethics Committees, provided separate and specific consent for such research is given.

Contraindications that generally make a deceased person ineligible to donate organs and tissues include (TSANZ 2004):

a) any history of malignant melanoma;

b) any history of metastatic malignancy;[10]

c) other non-curable malignancy (curable malignancy such as localised small kidney tumours, primary brain tumours, localised prostate cancer, colon cancer more than five years previously may be considered after careful risk/benefit analysis); and

d) active human immunodeficiency virus (HIV) infection.

In addition, Therapeutic Goods Administration[11] regulations should be consulted.

APPROACH TO THE CORONER

If the Coroner has jurisdiction to investigate a death or hold an inquest, the Coroner must give authority prior to removal of organs and tissues. The policies and processes for obtaining Coroner's authority vary between jurisdictions and, in some States, from area to area and should be ascertained in advance.

The Coroner should be informed precisely which organs and tissues (including subsidiary tissues for tissue typing and disease screening) it is proposed to remove from the deceased. Consent will be specific to these.

Depositions for the coroner stating the condition of the organs and tissues donated will be required in most instances from those responsible for their removal. These will be forwarded to the Coroner to become part of the coronial file. In some cases, the coroner may require that a pathologist be present at the time of organ or tissue removal.

AUTOPSY

Autopsy is desirable because information that can be obtained only at autopsy (for example, the presence of unsuspected malignancy) may be of great importance to potential or actual organ and tissue recipients. Even though the results of autopsy may be too late to affect the transplanting of solid organs or corneas, the results may be relevant in determining the post-transplant management of recipients, and may influence whether or not to transplant other tissues.

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[10] With the exception of corneas, which may be donated if metastatic malignancy is identified.

[11] The New Zealand and Australian Governments have agreed to establish a trans-Tasman therapeutic products agency which may replace the Australian Therapeutic Goods Administration in the lifetime of these guidelines.

Authority for autopsy

In non-coronial cases where donation is to occur and the deceased has not expressed a wish for, or consent to, autopsy, the next of kin should be approached to discuss the deceased person's and the family's views about autopsy. If the family agree to autopsy, consent should be documented.

3.5 MANAGEMENT AFTER DEATH

Following death and throughout the process of organ and tissue retrieval, the body of the deceased should be treated with respect and dignity. Only those organs and tissues for which written permission has been legally obtained may be removed[12] and sufficient records are kept to enable donated organs and tissues to be traced to recipients should this become medically desirable.

Clinical guidance on management after death is given in the ATCA guidelines for organ and tissue donation (see Appendix D) or may be sought from the retrieval team, the donor coordinator, the organ donation agency or the tissue or eye banks. The Australian Health Ministers' *Code of Ethical Autopsy Practice* provides guidance on the ethical conduct of autopsies (see Appendix D).

REMOVAL OF ORGANS

Removal of organs is carried out under normal operating theatre conditions and in accordance with procedures recommended by the retrieval team. The surgeon or medical practitioner is required to sight all of the documentation relevant to the donation process as per jurisdictional legislation and institutional protocol (see Chapter 4).

REMOVAL OF TISSUES

Tissues are collected, processed and stored in licensed tissue banks in accordance with ATBF or EBANZ standards and the local regulatory code. Local procedures should be developed in consultation with the specialist surgeons who will be transplanting the tissue.

In circumstances where there are appropriate facilities and medical supervision, trained technical staff may remove tissues. The procedure must be well-documented with the appropriate quality control and assurance mechanisms in place.

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[12] This applies also to organs and tissues removed for research purposes and forwarded to research facilities and programs.

Viewing the person's body

The family of the deceased should be given the opportunity to view the body after organ and tissue donation. Before the body is viewed, it should be restored to a semblance of normality so, other than sutures, it is altered as little as possible. The family should be advised about the body's appearance before the viewing. The family should also be offered support when viewing the person's body, preferably by the health professional who has been the family's main contact or another appropriately trained health professional, such as a bereavement counsellor.

4 IMPLICATIONS FOR INSTITUTIONAL PRACTICE

This chapter discusses the implications for institutions resulting from the ethical considerations given in Chapters 2 and 3. It provides discussion of:

a) the governance role of the designated officer, roles and responsibilities of other staff members involved in the donation process, and the ethical principles underlying these roles (Section 4.1);

b) the principles underpinning allocation of organs and tissues (Section 4.2);

c) ways in which the advice given in these guidelines can be implemented (Section 4.3).

In order for donation to be carried out ethically, processes need to be consistent, transparent and efficient.

Checklist for institutional ethical practice

- Enable effective identification of potential donors.
- Promote compassionate, ethical and sensitive treatment of the donor's family.
- Support fulfilment of ethical and legal requirements associated with determination of death and with organ and tissue donation.
- Ensure effective liaison among donor coordinators, transplant teams, and other clinical units for safe and timely retrieval and allocation of donor organs and tissues.
- Provide a supportive environment for the range of health professionals working with donor families.
- Ensure that, as far as reasonably possible, people are able to have their wishes about donation carried out, irrespective of the type of institution in which they die.
- Recognise the importance of the safety and health of the recipient patient.
- Adequate resourcing and support is essential to ethical practice in donation. Health services have a responsibility to ensure hospital resources allow for adequate staffing, ongoing professional development and strong governance in the short and long term.

LEGAL GUIDANCE

Legal requirements concerning the role of the designated officer and who may be appointed to this role vary between jurisdictions. Institutional protocols are required to follow the legislation of the State or Territory in which they are situated. Links to relevant legislation in each State and Territory are given in Appendix D.

4.1 ROLES AND RESPONSIBILITIES

Every institution in which organ and tissue donation takes place is responsible for ensuring that it is carried out in an ethically acceptable manner. Management-level actions that support ethical practice are:

a) clearly defining the role of the designated officer and ensuring that the person given this role has sufficient authority and experience to fulfil it;

b) clearly delineating the roles of the many professionals involved in the process of donation and transplantation;

c) providing ongoing training and support; and

d) supporting a team approach.

GOVERNANCE AND OVERSIGHT

The role of the designated officer or equivalent in providing approval and ensuring that processes are properly followed is specified in the legislation in each State and Territory. The designated officer cannot provide authority for removal of organs or tissues after death until he or she has made inquiries and is satisfied that:

a) death has been determined following established criteria;

b) confirmation of death is clearly documented in the medical record;

c) there is evidence of the deceased's donor intentions or, if there is no such evidence, there is evidence that the senior next of kin agrees to donation, and the nature of that evidence conforms to State or Territory legislative requirements;

d) either there is no reason to believe that a coroner has jurisdiction, or if they do, authority for removal of organs and/or tissues has been obtained from a coroner;

e) the process has been conducted with due concern for those involved (family members and health professionals), including clear delineation of roles between those caring for the patient and those procuring organs or tissues; and

f) the process followed is in line with institutional protocols, relevant guidelines and with jurisdictional legislation.

This oversight role requires that the designated officer be a senior staff member (preferably in a full-time tenured position) who is not likely to be involved in any of the steps of the organ donation process (eg care of the patient, informing consent, determination of death, organ and tissue retrieval, care of recipient, transplantation). The designated officer role should be supported by the institution (eg through adequate resourcing, availability of suitably trained delegates so that the duties of the designated officer can be covered on a 24-hour basis, and ongoing training).

HEALTH PROFESSIONALS INVOLVED IN DONATION

Intensive care team

For organ donation, intensive care specialists are likely to be the senior medical officers caring for patients up until death. Along with intensive care nurses, they are part of the team involved in supporting donor families through the process of certification of death and consent to donation.

Donor coordinator

Donor coordinators play a pivotal role in the process of organ and tissue donation. For organ donation, donor coordinators are likely to be called upon when a patient has been certified dead (eg following the second test for irreversible loss of all brain function) and the family has indicated an intention to proceed with organ and tissue donation. For tissue donation, donor coordinators are likely to be involved in the initial identification of a potential donor as well as the consent process and arranging surgical retrieval.

While responsibilities vary between jurisdictions and between institutions, they are likely to include:

a) consulting the AODR to gather evidence of the deceased's consent or intentions regarding organ and tissue donation;

b) providing information to the family to support informed decision-making and documenting formal consent to donation by the senior next of kin;

c) completing medical and social questionnaires to gather information on the suitability of organs and tissues for donation;

d) coordinating the process of allocation of organs as per Transplantation Society of Australia and New Zealand (TSANZ) and Australasian Transplant Coordinators Association (ATCA) protocols;

e) depending on the type of donation, liaising with tissue banks and ensuring that tissue donation and allocation follow accepted regulations;

f) arranging surgical teams, operating theatres, anaesthesia and pathology testing and liaising with immunology (for renal transplants);

g) providing for safe transport of organs according to accepted standards;

h) preparing the body for viewing following retrieval of organs and tissues;

i) providing ongoing care to the family (including informing them of available support services and other activities to honour donors, providing feedback on the success of the transplantation and acting as a go-between for donor families and recipients to preserve confidentiality);

j) supporting other health professionals, including providing information, feedback and support to those involved in the process; and

k) maintaining records on donation within their institution.

Others involved in the care of donors, recipients and their families and carers

a) Regional or area nurses — Undertake a regional donor coordinator role in hospitals in areas where the donor coordinator performs a central management role.

b) Other donor institution medical and nursing staff — Can be involved in supporting donor families, as deaths suitable for tissue donation can occur in almost any ward.

c) Social worker — Provides support to families and assistance with practical issues.

d) Coroner — Investigates the circumstances of unnatural and unexplained deaths and reports the cause. In these cases, the Coroner must give authority before donation may proceed and can impose restrictions on what can be donated.

e) Recipient (or transplant) coordinator — Provides information and support to the transplant recipient and family and coordinates the transplant operation. The recipient is usually being prepared for their operation at the same time the donor operation is occurring.

f) Other health professionals and hospital staff — Might be involved less directly in donation, including clinical teams involved in care beyond the intensive care team, and other hospital employees (eg desk clerks).

g) Transplant team — Care for patients with end stage organ failure and organ transplant recipients. Members of the team may advise on donor management after the certification of death but may not be involved in the care of the donor or decision-making about discontinuation of treatment.

PRINCIPLES UNDERLYING RESPONSIBILITIES

Specific roles of the health professionals involved in donation vary by jurisdiction and institution. Local availability of resources also influences roles and responsibilities. However the process is organised, the following ethical criteria should be observed:

a) there is complete separation of roles between those involved in the care of the patient and family and those involved in organ and tissue retrieval or care of the recipient;

b) health care professionals who make the initial approach to the family about organ and tissue donation have sufficient experience and/or have undertaken specific training in the task;

c) the designated officer performs a governance role, ensuring that all steps in the process are followed absolutely before giving authority for retrieval to proceed, and should have training and adequate authority to perform the role properly. The role should not be delegated to a person without sufficient training or responsibility;

d) the confidentiality of both donors and recipients is maintained; and

e) records of the process are kept with due regard to confidentiality and privacy.

4.2 ALLOCATION OF ORGANS AND TISSUES

Organs and tissues must be allocated justly and in a way that is transparent and explained to potential recipients. This is important to maintain respect for the system of obtaining organs and tissues for the treatment of those who are in need of a transplant.

The key principle underpinning the allocation of organs and tissues is that there should be no discrimination between potential recipients on the basis of:

a) race, nationality, religious belief, gender, marital status, sexual orientation, social status, disability or age (except where conditions associated with the patient's age directly determine the likelihood of a poorer outcome);

b) willingness of family members to be donors (after death);

c) need for a transplant arising from the patient's past behaviour;

d) capacity to pay; or

e) willingness to participate in experimentation, except where it is a trial for a novel transplant procedure that requires follow-up and audit.

Allocation of organs is a complex process that depends on a range of factors besides medical need and capacity to benefit. There is an unpredictable element in the process in that organs have to be matched to recipients. Potential recipients may wait variable periods of time on waiting lists. This waiting time may be unrelated to their medical need, but dependent upon a matched organ becoming available.

Transplant units should use organs as best they can, and balance medical need with the likelihood of successful transplantation. It is legitimate that the following criteria be taken into account in considering potential recipients:

a) 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;

b) important medical factors, such as the closeness of tissue-matching and matching of organ quality with the patient's medical status to maximise the likelihood of success;

c) the urgency of a transplant given the likely degeneration of health without transplant therapy, especially if patient survival is immediately threatened by that degeneration;

d) need in terms of how sick the patient is without transplant therapy, and the prospects for transplant therapy producing a better outcome; and

e) logistic factors in making the transplant available to the recipient within an appropriate time frame.

Protocols for the allocation of specific organs and tissues have been developed by TSANZ, the ATBF and the EBANZ (see Appendix D for contact details of these organisations).

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 uphold the principles outlined above.

Potential recipients should be informed about the allocation process for the organ or tissue that they need, and specific factors that apply in their situation. This includes:

a) the information that patients may become too ill, either temporarily or permanently, to be considered for transplantation;

b) education about transplantation to ensure that patients are not excluded from the waiting list because they do not understand the nature of the procedure or the requirement for ongoing medical monitoring; and

c) explaining to patients from rural and remote areas that due to the timeframes involved in transplantation, they may have to leave home for extended periods of time in order to be closer to the transplant unit.

With increases in rates of living donation in which directed donation is accepted, deceased directed donation is emerging as an issue for community discussion (see Appendix C).

4.3 LOCAL IMPLEMENTATION OF THESE GUIDELINES

Institutions that provide care to patients who may become potential donors need to develop and implement a policy and protocols to support ethical practice in the area of organ and tissue donation. Institutions also have a responsibility to support staff involved in organ and tissue donation through ongoing training, counselling and other suitable assistance.

QUALITY MANAGEMENT

Policy

An institutional policy on organ and tissue donation that incorporates the principles outlined in these guidelines will assist in supporting ethical practice. The policy should be developed in accordance with national and State or Territory guidelines and jurisdictional legislation (see Appendix D). It should be regularly reviewed to ensure currency.

Protocols

The policy should be incorporated into institutional practice through a set of protocols — for organ donation, protocols will be particularly applicable in the intensive care unit; for tissue donation protocols are likely to apply across the hospital. Areas to be covered by institutional protocols are likely to include:

a) responsibilities of different categories of staff;

b) consulting the Australian Organ Donor Register and contacting the next of kin;

c) systems for effective liaison between hospitals and other institutions;

d) guidelines to be referred to in determining death, managing the deceased before organ and tissue retrieval, and communicating with the donor family;

e) training requirements for staff, in particular those who will be raising the issue of organ donation with relatives;

f) development of materials to meet linguistic and cultural needs of the institution's patient population; and

g) record keeping and data collection.

Audit

There should also be systems in place to support:

a) auditing of the process of organ and tissue donation within the institution; and

b) auditing of the process of allocation of organs.

These aspects should be included in peer review and internal medical audit activities as part of the routine quality review processes of the institution.

Community education

Consideration could also be given to activities to raise community awareness about organ and tissue donation and transplantation, particularly targeting sub-groups that may have specific information needs. Increased community awareness about organ and tissue retrieval following death determined by irreversible cessation of circulation is likely to assist all those involved.

SUPPORTING STAFF

Training

Training required will depend on the professional's role in the organ and tissue donation process, for example:

a) orientation to the designated officer position should include training to ensure that the person has full knowledge of the legal responsibilities involved and understands the organ and tissue donation and transplantation process; and

b) health professionals who are likely to be the main contact for families during the organ and tissue donation process should be supported in accessing training in the area, including bereavement counselling, if they do not already have significant experience (training is available through organisations listed in Appendix D).

Training regarding organ and tissue retrieval following death determined by irreversible cessation of circulation should be a priority at all levels within the hospital system and for medical and allied health educational bodies.

Counselling

Counselling and other suitable assistance should be available for staff members affected by organ and tissue donation. Availability of such services to operating room staff is particularly important. Organised debriefing sessions may be helpful in providing an opportunity for formal peer support.

APPENDICES

A MEMBERSHIP AND TERMS OF REFERENCE OF THE WORKING PARTY

Dr Peter Joseph (Chair)	Health Advisory Committee member, 2003–2006 Triennium
Dr Wendy Rogers (Deputy Chair)	Australian Health Ethics Committee member, 2003–2006 Triennium
Ms Marcia Coleman	Chairperson, Australians Donate
Dr Geoffrey Dobb	Australian and New Zealand Intensive Care Society (ANZICS) nominee
Dr Gerard O'Callaghan	Australian and New Zealand Intensive Care Society nominee
Professor Peter MacDonald	Transplantation Society of Australia and New Zealand (TSANZ) nominee
Ms Jean Murray	Australian Health Ministers' Advisory Committee (AHMAC) Organ Donation Working Group nominee
Ms Mardi Thompson	Consumers' Health Forum of Australia nominee
Dr Nicholas Tonti-Filippini	Australian Health Ethics Committee member, 2003–2009 Triennia
Dr Deborah Verran	Transplantation Society of Australia and New Zealand nominee
Mr Daniel Winters	Australasian Transplant Coordinators' Association (ATCA) nominee

Secretariat

Ms Sharon Hill (to May 2006)

Ms Julie Taylor (from May 2006)

Technical writers

Ms Elizabeth Hall	Ampersand Editorial & Design
Ms Jenny Zangger	Ampersand Editorial & Design

TERMS OF REFERENCE

Role

The primary role of the Organ Donation Working Party is to review the National Health and Medical Research Council (NHMRC) publication *Recommendations for the donation of cadaveric organs and tissues for transplantation* (1996), in accordance with a request from the Australian Health Ministers' Advisory Council.

Functions

In reviewing this publication the Working Party will:

a) take into account new developments and emerging issues in the donation of cadaveric organs and tissues;

b) consult with key stakeholders;

c) consider the following 1997 Australian Health Ethics Committee (AHEC) publications:

- *Donating Organs after Death: Ethical Issues,*
- *Ethical Issues in Donations of Organs and Tissues by Living Donors,*
- *Ethical Issues Raised by Allocation of Transplant Resources,* and
- *Certifying Death: the Brain Function Criterion;* and

d) make recommendations to AHEC in relation to the five NHMRC organ donation documents and any revisions necessary.

LINE OF REPORTING

The Working Party will regularly report on its progress to AHEC and seek endorsement of its activities and recommendations.

B AHMC RECOMMENDATIONS

These recommendations were noted by the Australian Health Ministers' Conference in January 2005, and intended for future release after the AODR upgrade was completed. They were developed by the Australian Health Ministers' Advisory Council Organ Donation Working Group to ensure national coherence and to help guide future policy development and practice. They were the subject of a communiqué released by Australian Health Ministers at the time.

1. Organ and tissue donation should be routinely discussed with the family in all cases where a medically suitable donor is identified.
2. Professionals involved in the organ and tissue donation process and who approach donor families should demonstrate a professional commitment to organ and tissue donation and should have received specialised training to provide them with the necessary knowledge and skills.
3. The AODR should be routinely consulted whenever a medically suitable donor is identified prior to discussing organ and tissue donation with the family.
4. In order to facilitate AODR consultation, there should be ready access to the register for intensivists, donor coordinators and other appropriate health professionals as nominated by their jurisdiction and approved by Medicare Australia. Register information should be shared across the team.
5. A thorough explanation of the brain injury and of the concept of brain death should precede any discussion of organ donation.
6. When the intention of the potential donor is known, the family should always remain involved in the process of giving effect to those intentions. They should be asked if they are aware of any changes in the expressed consent of the potential donor.
7. When the intention of the potential donor is not known, information should always be presented with due consideration to family circumstances so as to ensure that their views are based on an accurate understanding of the relevant facts, that their concerns have been adequate addressed, and to provide them with an opportunity to clarify any questions they may have.
8. A sincerely held objection by the family should be respected even if it is in conflict with the known intention of the potential donor.
9. Families should be kept informed about the condition of the potential donor and be given timely and detailed information. All reasonable attempts should be made to maintain continuity in communication with family and whenever possible, the same clinician should be responsible for communication with the family.

10 Appropriate bereavement counselling and follow-up services by qualified staff should routinely be offered to all families who are approached for organ and tissue donation. These services should continue to be available to meet their short and longer term needs whether or not donation took place.

11 Jurisdictions ensure that hospitals and institutions dealing with organ or tissue donation adopt local processes consistent with these recommendations.

C ISSUES FOR FURTHER COMMUNITY DISCUSSION

There are a number of controversial ethical issues associated with organ and tissue donation, including:

a) ways to increase the low rate of donation in Australia while balancing the rights of donors and recipients;

b) ad hoc contact between donor families and recipients;

c) novel therapies such as transplantation of limbs and faces;

d) deceased directed donation; and

e) commercialisation of tissue banking.

This brief discussion summarises some of the arguments around these issues and is included to foster and assist community debate.

LOW RATES OF ORGAN AND TISSUE DONATION

Compared with many developed countries, Australia's donor rate is low and has remained so despite recurrent publicity campaigns promoting organ and tissue donation. The reasons for the low rate are not clear, as numerous community surveys have found that most people support donation and would want their organs and tissues donated after death.

A recent article highlighted the considerable variation in donation rates within Australia and between teaching hospitals in capital cities, suggesting that barriers to increased organ donation exist within the hospital system (Mathew et al 2005).

As outlined in this report, AHMC recommendations in 2004 led to changes to the AODR which make it more likely that people's expressed wishes about donation will be carried out. This protects the rights of donors. Some suggest that the Australian community also has an ethical and moral obligation to transplant recipients. For a number of conditions (eg end stage renal failure), transplantation is considered best practice. However, the low donation rate means that many people are not able to have the preferred treatment and may die while waiting for a deceased donor organ to become available.

Consideration should be given to models that break down barriers to organ and tissue donation. It is also clear that further research is required into why donation and transplantation rates are particularly low among Aboriginal and Torres Strait Islander peoples and other culturally and linguistically diverse communities.

Opting in/opting out

The current system of organ donation in Australia — where individuals are asked to register their willingness to be a donor after death — is referred to as "opting in". It has been suggested that the "opting out" or presumed consent model used in some other countries might increase the availability of organs and tissues for transplantation.

Under a system of "opting out" or "presumed consent" every person is deemed to have given their consent to organ donation unless they had specifically recorded their unwillingness to give organs in writing. Opt out systems can be "hard", as in Austria, where the views of close relatives are not taken into account or "soft" as in Spain, where relatives' views are sought.

Supporters of this system argue that consent to donation is implicit and seen as the norm rather than the exception and relatives are relieved of the burden of crucial decision-making at a traumatic time.

However the system may cause distress if relatives are not consulted before organ procurement. This in turn could lead to adverse publicity and loss of good will towards organ donation among community members, as well as having an impact on their trust and respect for the health system. There could also be medical risks to recipients, as donor families are a valuable source of information about the previous health of the deceased.

The system also carries the potential for individuals who have not understood the policy or were ignorant of its existence to not register their objection and unwittingly become donors after death.

It is because of these concerns that in the majority of countries operating an opt out system, health care professionals still ask the family for permission to remove organs and tissues.

Large disparities in organ donation rates exist throughout the world, irrespective of the legal regulation of organ donation. Some countries that have opt out systems have high donation rates but there is no clear evidence that opt out is the sole factor — for example Sweden has an opt out law but has a lower donation rate per million population than that of the United Kingdom, which does not. Within almost all countries, large local variations exist in donation rates, despite a common legislative background.

Different cultural attitudes to bodily integrity, greater provision of intensive care beds, more progressive donation programs and road safety all play a part in determining donation rates. However, the most important factor so far identified in obtaining agreement for donation is to ensure that the relatives of potential organ donors are approached by someone with sufficient experience or specific training for the purpose.

CONTACT BETWEEN DONOR FAMILIES AND TRANSPLANT RECIPIENTS

Confidentiality provisions in the Australian Human Tissue Acts prohibit health professionals from publicly identifying donors and recipients of transplanted tissue. This prevents the creation of institution-based contact registers that allow links to be made. However, this type of contact is a significant issue for some donor families and recipients.

Current situation

Currently, donor families and transplant recipients who want to correspond approach their State or Territory Organ Donation agency for advice and assistance. The agencies have systems whereby letters without identifying details can be passed between donors and recipients. This process allows for counselling about the risks of contact and how they can be avoided, and also ensures that the correspondence is entirely voluntary on both sides and that letters passed on do not carry actual or implied obligations on the other party. Increasingly, donor families and recipients are using their own initiative and means to make direct contact, through information gained using the internet and the media. These contacts are being made without the benefit of mediators or counselling to help work through the emotional impact of any disappointment or unmet expectations.

Mutual consent register

Although the law prevents governments and health agencies from establishing contact registers, a mutual consent register can be legally provided by a community group. Mutual consent registers allow the sharing of information, and even the possibility of identification and an arranged meeting, and may meet the needs of some donor families and recipients for greater knowledge. If resourced, it could provide a formal and caring framework to facilitate what is already happening on an *ad hoc* basis through the internet and media.

Formal registers allow a donor's family, if they wish, to find out about the outcome of their relative's donation and how the transplant has changed the life of the transplant recipients. Recipients may also benefit, as the register would allow them to know about the donor and express gratitude for the donation to the family if they wish.

There are potentially harmful consequences of contact without the professional assistance of a formal register. Donor families may be distressed to discover that the transplant was rejected or that the recipient died. One party (either from the donor's family or the recipient) may seek inappropriate emotional support or a relationship that becomes unwelcome to the other party. A time delay mechanism preventing contact in the immediate post-transplant period may help to ensure that the pros and cons are thoroughly considered before seeking contact.

A mutual consent register could follow the same process and rules of practice that have been established in some jurisdictions for permitting contact between adoptees and their relinquishing parents. It is important that records be kept in such a way that, should a mutual contact register be established in the future by legislative change, the necessary information could be provided.

NOVEL THERAPIES

An increasing range of deceased donor organs and tissue transplants is being performed overseas and likely to be introduced in Australia. Some of these transplants are highly experimental and raise additional ethical concerns about obtaining truly informed consent.

An example of a novel therapy is composite tissue allotransplantation (CTA). In September 1998 the first human hand transplant was carried out in Lyon, France. Since then hand transplants, a laryngeal transplant and a tongue transplant have been performed. A partial facial transplant (skin plus underlying tissue) has also occurred.

In most instances the aim of CTA surgery is to improve the quality of life and not to cure disease or save life. No CTA has been carried out in Australia to date.

The recent nature of these procedures means that there is limited understanding of the associated long-term physical and psychological outcomes.

Some issues raised by novel therapies include:

a) the balance between improved quality of life and the high risk of complications or rejection and the long-term risk from lifelong immunosuppression (organ dysfunction, infections or cancer);

b) the psychological impact on the recipient and on the donor family; and

c) the validity of consent from potential recipients, given the uncertainties about the risks and benefits that accompany the highly experimental character of the procedure.

DECEASED DIRECTED DONATION

Current practice is based on the premise that donation of tissues and organs is an unconditional altruistic act. In Australia and many other countries, donated organs and tissues are allocated to the most suitable people on the waiting list. The donor (through previously expressed wishes) or family cannot impose conditions or specify potential recipients. However, directed deceased donation is emerging as an issue for community debate.

a) The growing use of living donors has given rise to more controversial methods of organ and tissue solicitation that are also being applied to deceased donation, including private advertising, community-based groups soliciting on behalf of individuals and internet sites that link patients with potential donors. However, solicitation of organs and tissues on behalf of a specific transplant candidate is unethical as it bypasses accepted ethical principles of allocation and favours those who have sufficient resources and/or social skills to attract publicity.

b) Most living donation is directed within the donor's family or social circle, and some argue that directed deceased donation to a relative or friend in need of a transplant is ethically no different. This would only be so if the following conditions are met:

   — there is evidence that the person wished to donate organs and tissues to the general pool after death;

   — there is evidence (eg through a living will or advance directive) that the person expressed a preference for certain organs or tissues to be donated to a specific relative or friend in need of a transplant;

   — the transplant candidate is medically suitable and consents to receiving organs or tissues from that donor; and

   — the family is not imposing conditions on the deceased person's behalf.

COMMERCIALISM IN TISSUE BANKING

Currently, the Australian Human Tissue Acts prohibit trading in human tissue, but allow recovery of legitimate costs associated with processing and treatment. While tissue banks are run as not-for-profit operations, relationships are formed with for-profit companies when this is the only option for developing particular human tissue-derived products or devices.

This area requires continuing community debate and legislative oversight. The experience overseas indicates that commercialism in tissue banking can lead to undue focus on revenue rather than on the benefits to recipients and the community. In the US, which has a similar legal framework to Australia, tissue banking is a major industry and there have been examples of unethical behaviour by individual tissue banks in their relationships with commercial groups.

While there are many benefits to the community from the production and use of therapeutic devices where these are superior to synthetic products, it is essential that commercial imperatives do not overtake the ethical principles on which donation and tissue banking are based. Tissue commercialisation raises potential conflicts with these ethical principles, as indicated by the following points.

a) *Consent issues* — as consent for release of donated tissues for manufacture of therapeutic devices is not covered by the AODR, there would need to be mechanisms for obtaining separate and explicit consent for use of tissues for the manufacture of therapeutic devices.

b) *Need to protect the spirit of altruism* — it is vital that the altruistic spirit that underpins donation in Australia is maintained; some degree of scrutiny of commercial processes would be needed to ensure that altruism is not eroded (eg by on-selling of donated tissues).

c) *Effect on the public perception of organ and tissue donation* — great care would need to be taken in implementing commercial arrangements, as any public perception that there is trade in human body parts could undermine the established system of organ and tissue donation, including blood and bone marrow donation.

d) *Conflicts of interest* — Great care would need to be taken to ensure that commercial arrangements avoid any financial conflicts of interest. There should be clear separation of roles, especially for any practitioners involved in collection, processing and clinical use of therapeutic products and devices.

e) *Need to protect recipients from harm* — given the risks to people who receive products sourced from donated body parts, there would be a need for standards and mechanisms for screening of donors and production of therapeutic devices using donated tissues.

D FURTHER SOURCES OF INFORMATION

AGENCIES INVOLVED IN THE SECTOR

Organisation	**Website**
Australasian Donor Awareness Programme	www.adapt.asn.au
Australasian Tissue Banking Forum	www.atbf.org.au
Australasian Transplant Coordinators' Association	www.atca.org.au
Australian and New Zealand Intensive Care Society	www.anzics.com.au
Australian and New Zealand Organ Donation Registry	www.anzdata.org.au
Australian College of Critical Care Nurses	www.acccn.com.au
Australian Donor Awareness Programme	www.adapt.asn.au
Australian Organ Donor Register	www.medicareaustralia.gov.au
Australians Donate	www.organdonation.org.au
International Transplant Coordinators Society	med.kuleuven.be/itcs
Joint Faculty of Intensive Care Medicine	www.jficm.anzca.edu.au
Kidney Health Australia	www.kidney.org.au
Transplant Australia	www.transplant.org.au
Transplant Nurses Association Inc	www.tna.asn.au
Transplantation Society of Australia and New Zealand	www.racp.edu.au/tsanz

Contact details for organisations that do not have a website (such as the Eye Banks Association of Australia and New Zealand) are available through the Australians Donate website.

STATE/TERRITORY ORGAN DONATION AGENCIES

Donate West	www.donatewest.health.wa.gov.au
LIFEGift (Victoria and Tasmania)	www.organdonor.com.au
Organ Donation Network of NSW and ACT	www.organ.redcross.org.au
LifeNet (NT)	www.health.nt.gov.au
Queenslanders Donate	www.health.qld.gov.au/ queenslandersdonate
South Australian Organ Donation Agency	Website address to be included when launched

KEY INFORMATION SOURCES

Guidelines

AHMAC (2002) *The National Code of Ethical Autopsy Practice*. South Australian Department of Human Services, on behalf of the Australian Health Ministers' Conference.

ANZICS (1998) *Recommendations on Brain Death and Organ Donation.* Australian and New Zealand Intensive Care Society, Melbourne. (under review)

ATCA (2006) *National Guidelines for Organ and Tissue Donation.* Australasian Transplant Co-ordinators Association.

EBANZ (2005) Medical Standards for Eye Donation and Ocular Tissue Banking. 1st Edition.

NHMRC (2001) *Organs Retained at Autopsy. Ethical and Practical Issues.* Commonwealth of Australia.

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 (2004) *Post-coma Unresponsiveness (Vegetative State)*: A Clinical Framework for Diagnosis. Information paper. Commonwealth of Australia.

NHMRC (2007) *Organ and Tissue Donation by Living Donors: Guidelines for Ethical Practice for Health Professionals.*

NHMRC (revised edition forthcoming 2006) *National Statement on Ethical Conduct in Research Involving Humans.*

NSW Health (2005) *Guidelines for End-of-life Care and Decision-making.* NSW Health Department, Sydney.

TSANZ (2002) *Organ Allocation Protocols.* Transplantation Society of Australia and New Zealand, Sydney. www.racp.edu.au/tsanz/oapmain.htm

WHO (1991) *Guiding Principles on Human Organ Transplantation.* www.who.int/ethics/topics/transplantation_guiding_principles/en/print.html — accessed 29 June 2006.

Cultural competency

AHMAC Standing Committee for Aboriginal and Torres Strait Islander Health Working Party (2004) *Cultural Respect Framework for Aboriginal and Torres Strait Islander Health, 2004–2009.* Department of Health, Adelaide. www.health.sa.gov.au

Cass A et al (2002) Sharing the true stories: improving communication between Aboriginal patients and healthcare workers. *MJA* 176: 466–70. www.mja.com.au

NHMRC (2006) *Cultural Competency in Health: A Guide for Policy, Partnerships and Participation.* www.nhmrc.gov.au

Queensland Health (2003) *Cultural Diversity — A Guide for Health Professionals.* www.health.qld.gov.au/multicultural/cultdiv/default.asp

Royal Australasian College of Physicians (2004) *An Introduction to Cultural Competency.* www.racp.edu.au

Rundle A, Carvalho M, Robinson M (eds) (1999) *Cultural Competence in Health Care: a Practice Guide.* Jossey Bass, SF

TRAINING OPTIONS

Health professionals should contact the relevant organisation (see above) to make enquiries about training options.

LEGISLATION

The legal aspects of organ and tissue donation — determination of death by the brain function criterion, consent processes and ante-mortem interventions — are covered by a range of legislation in each jurisdiction. Following are online sources of legislation for each jurisdiction.

Commonwealth	www.scaleplus.law.gov.au
New South Wales	www.legislation.nsw.gov.au
Victoria	www.dms.dpc.vic.gov.au
Queensland	www.legislation.qld.gov.au
Western Australia	www.slp.wa.gov.au/statutes/swans.nsf
South Australia	www.parliament.sa.gov.au
Tasmania	www.thelaw.tas.gov.au
Northern Territory	www.nt.gov.au/lant/hansard/hansard.shtml
Australian Capital Territory	www.legislation.act.gov.au

E PROCESS REPORT

Following the publication of the NHMRC's *Recommendations for the Donation of Cadaveric Organs and Tissues for Transplantation* in 1996, the Australian Health Ethics Committee (AHEC) produced four organ donation books in 1997:

a) *Donating Organs after Death: Ethical Issues*;

b) *Ethical Issues in Donations of Organs and Tissues by Living Donors*;

c) *Ethical Issues Raised by Allocation of Transplant Resources*; and

d) *Certifying Death: The Brain Function Criterion*.

In August 2004, the Organ Donation Working Group of the Australian Health Ministers' Advisory Council (AHMAC) requested AHEC consider reviewing and re-issuing the NHMRC's *Recommendations for the Donation of Cadaveric Organs and Tissues for Transplantation*.

This request coincided with approval of the July 2005 change to the Australian Organ Donor Register from one of intent to one of consent. AHMAC sought advice from AHEC as to whether this change led to any substantial inconsistencies with the content of the NHMRC *Recommendations*, including the document's likely content after review. AHEC provided this advice to the Chair of AHMAC in a letter dated 24 June 2005.

In accepting the task of revising the NHMRC *Recommendations*, AHEC decided also to revise the four discussion papers. The Organ Donation Working Party was established in early 2005. The Working Party revised the five documents into four new documents: two sets of guidelines aimed at professionals (one on deceased and one on living organ and tissue donation), and two new booklets for the general public (one on deceased organ and tissue donation, and the other on living organ and tissue donation).

LITERATURE SEARCH

Relevant articles were drawn from national and international literature and examined, as were a variety of national and international organisations' views on organ donation.

CONSULTATION

Targeted consultation 2002

In the course of developing this document, the AHEC Working Party reviewed the results of a public consultation process undertaken in 2002 by a previously constituted organ donation working party (which, due to resource constraints, had discontinued work on this project). This consultation focussed on the four AHEC discussion papers and did not seek comment on the NHMRC *Recommendations* document.

The 25 submissions received largely supported revision of the documents, highlighting areas where the information provided was not in line with practice or legislation at that time. The need for the target audience to be stated and for suitable language to be used were also noted.

Targeted consultation of relevant organisations

During February and March 2005, 91 organisations were asked to provide initial comments on the five existing organ donation documents. These organisations comprised six Working Party member organisations; seven State/Territory health departments; six other government organisations; seven State/Territory organ donation services; 40 other health and medical organisations; 21 transplantation units; and four Aboriginal and Torres Strait Islander contacts.

The submissions supported revision of the NHMRC *Recommendations,* to bring the document in line with current practice and legislation, while continuing to provide a framework for ethical practice. The main areas suggested for inclusion in the revised document were donation following cessation of the circulation, changes to the Australian Organ Donor Register, and sensitivity to different cultural and religious perspectives. There was general support for combining the *Recommendations* document and the four AHEC discussion papers though concern was expressed about the need to provide information suitable to different target audiences (health professionals, community).

Targeted consultation of donor family support organisations

In August and September 2005, 14 relevant individuals and organisations supporting donor families were asked to identify issues for inclusion in the four new documents.

Public consultation 2006

In February 2006, the guidelines and the community booklet derived from the guidelines were advertised for public consultation. Submissions were received from 73 organisations and individuals.

The main areas for revision identified in consultation submissions were the need to:

a) improve consistency and accuracy of terminology;

b) update data;

c) include discussion about low rates of donation in Australia;

d) clarify discussion on informed decision-making;

e) place greater emphasis on the importance of cultural appropriateness in communication and information provision;

f) separate discussion of donation following death determined by loss of all brain function from that following death determined by irreversible cessation of the circulation;

g) incorporate material specific to tissue donation (including corneal donation)

h) include discussion on bereavement counselling;

i) improve applicability of guidelines nationally (in context of varying legislation); and

j) improve layout and accessibility.

In light of these comments, the guidelines were revised with the aims of:

a) refining use of terminology;

b) including more information on the scope of the document;

c) including 2005 data from the 2006 ANZOD report;

d) expanding the section on issues for community discussion to include more information on rates of donation in Australia;

e) summarising the main ethical points in Chapters 2, 3 and 4 through the inclusion of ethical checklists;

f) separating discussion of donation following death determined by loss of all brain function from that following death determined by irreversible cessation of the circulation;

g) incorporating material specific to tissue donation where there are ethical issues involved;

h) reworking discussion of antemortem procedures to more accurately reflect the legal situation;

i) reducing clinical content and referring instead to relevant guidelines;

j) reducing specific comments on legislation and referring to variations more widely;

k) simplifying language and improving grammar;

l) enhancing navigation within the document through the use of running footers and tabsheets; and

m) improving layout.

DISSEMINATION AND IMPLEMENTATION

A plan for dissemination and implementation will be included in the final versions of these guidelines. It is anticipated that the final document will be disseminated to all stakeholders involved in the consultations, relevant professional colleges, State/Territory health departments. The document will also be available for downloading from the NHMRC website.

REVIEW

In line with NHMRC policy, this document will be reviewed five years after its publication.

GLOSSARY

Autopsy	An examination of the body after death to determine the cause of death and/or to discover and describe pathological processes present in the body at the time of death.
“Brain death”	“Brain death” is a commonly used term for death determined by the irreversible loss of all function of the brain. It must be distinguished from severely brain damaged states such as permanent or persistent coma or unconsciousness, post-coma unresponsiveness (vegetative state) or minimally conscious state.
“Cardiac death”	“Cardiac death” or “non-beating heart death” are terms for death determined upon irreversible cessation of circulation. Criteria for diagnosing cardiac death clearly differentiate this from other states such as irreversible cardiac disease in which circulation is failing or is maintained artificially, or where cessation of circulation is predicted but has not yet occurred.
Death	Death is the final cessation of the integrated functioning of the body. Integrated functioning is a characteristic of living beings. Death is observed to have occurred when there is irreversible loss of brain function or irreversible cessation of circulation.
Death determined by irreversible loss of all brain function	Death after loss of all brain function is determined when a person receiving artificial oxygenation is diagnosed independently by two experienced doctors as having permanently lost all function of the brain. When loss of all brain function occurs, control of the functions of the body ceases and the functions of the body are no longer integrated. In that state the individual organs of the body may live temporarily, if mechanical support is provided and circulation continues.

Death determined by irreversible cessation of circulation	Death after irreversible cessation of circulation is determined when circulation of blood through the body has permanently ceased. Loss of circulation is the point at which the organs lose function and begin to die. It is possible, soon after loss of circulation to retrieve some individual organs and to maintain them for a time outside the body.
Deceased donor	A person who gives organs and/or tissues after death for the purpose of transplantation into another person.
Designated officer	A member of hospital staff who is officially appointed to be responsible and accountable under State legislation for the process of organ and tissue donation in that hospital. Responsibilities of a designated officer are discussed in Section 4.1.
Donor coordinator	A person whose role is to facilitate the organ and tissue donation process by acting as the liaison between the donor hospital, donor family and transplant centre(s).
Maastricht categories	An international meeting on organ donation after cessation of the circulation held in Maastricht in 1995 identified four categories of potential donors (Kootstra et al 1995), to which a fifth category was added in 2003. These are described as either uncontrolled (Categories I/II and V) or controlled (Categories III/IV) donors. Category I: dead on arrival Category II: unsuccessful resuscitation Category III: awaiting cardiac arrest Category IV: cardiac arrest in a brainstem dead cadaver Category V: unexpected cardiac arrest in a critically ill patient.
Organ	A part of the body that performs vital function(s) to maintain life. These include the kidney, heart, lung, liver and pancreas.
Recipient	A person who receives organs and/or tissues from another person (the donor).

Tissue	A group of specialised cells (eg cornea, heart valves, bone, skin) that perform defined functions.
Tissue typing	The process of laboratory testing to determine the tissue groups of a potential donor, and to perform a cross-match between the donor and matched recipients to confirm the absence of reactivity between them. The cells used for tissue typing are obtained from the blood or from the lymph glands and spleen removed at the time of organ and tissue retrieval.
Warm ischaemic time	The time from irreversible cessation of circulation (and non-perfusion of organs in situ) until commencement of preservation solution for organ procurement.

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ABBREVIATIONS AND ACRONYMS

ACCCM	American College of Critical Care Medicine
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
ANZCOTR	Australia and New Zealand Cardiothoracic Organ Transplant Registry
ANZICS	Australian and New Zealand Intensive Care Society
ANZOD	Australia and New Zealand Organ Donor Registry
AODR	Australian Organ Donor Register
ATBF	Australian Tissue Banking Forum
ATCA	Australasian Transplant Coordinators' Association
CTA	composite tissue allotransplantation
EBANZ	Eye Banks Association of Australia and New Zealand
HIV	human immodeficiency virus
NHMRC	National Health and Medical Research Council
SCCM	Society of Critical Care Medicine (US)
TSANZ	Transplantation Society of Australia and New Zealand
WHO	World Health Organization

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