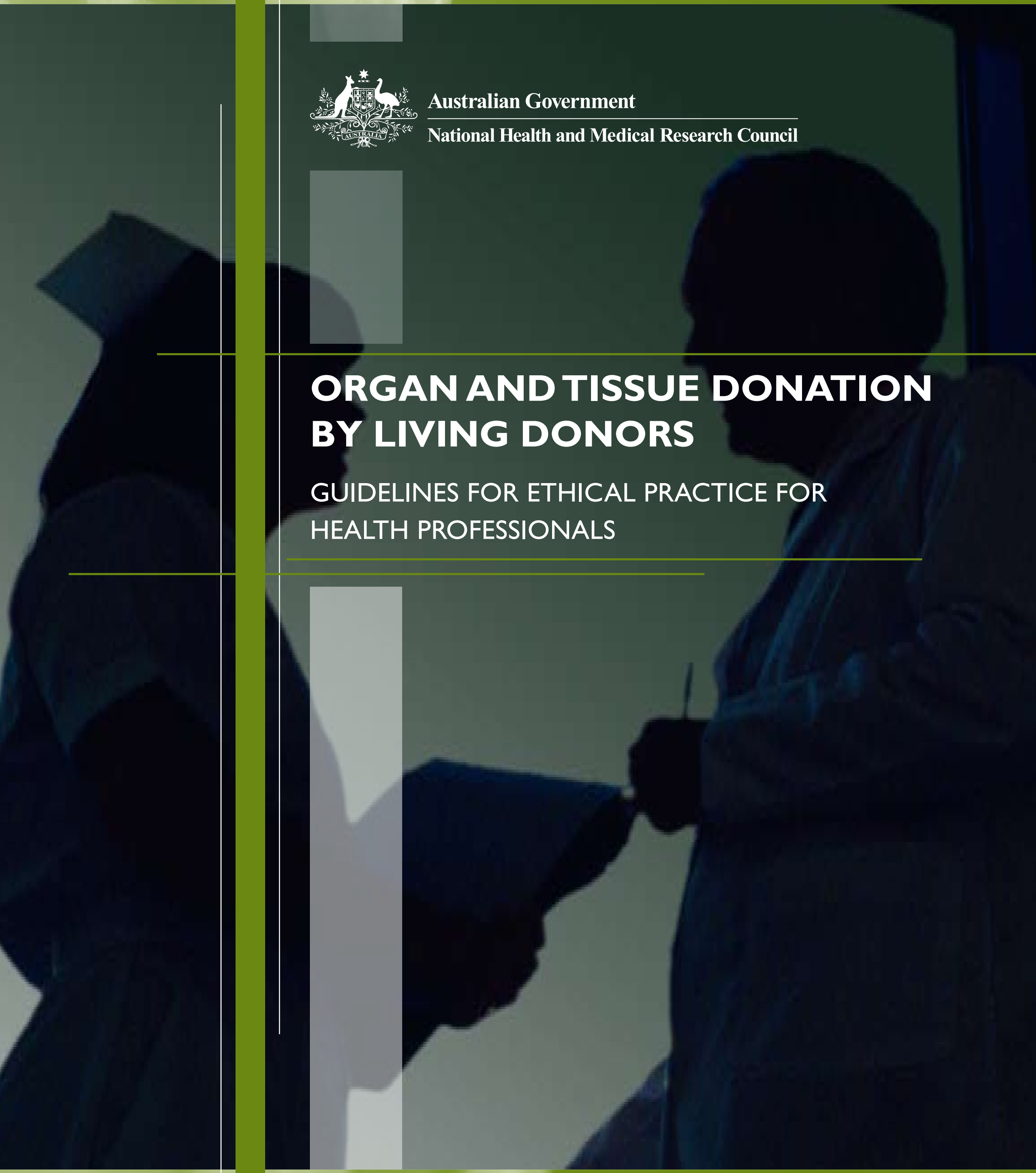

Australian Government

National Health and Medical Research Council

# ORGAN AND TISSUE DONATION BY LIVING DONORS

## GUIDELINES FOR ETHICAL PRACTICE FOR HEALTH PROFESSIONALS

WORKING TO BUILD A HEALTHY AUSTRALIA

Australian Government

National Health and Medical Research Council

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## GUIDELINES FOR ETHICAL PRACTICE FOR HEALTH PROFESSIONALS

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# INTRODUCTION

Organ and tissue transplantation can be an effective treatment for many patients, including those facing illness, disability or premature death through organ or tissue failure. Most transplanted organs and tissues come from deceased donors. Living donation offers an alternative for patients awaiting transplantation from a deceased donor, increases the existing donor organ and tissue supply and provides a source of tissues that cannot be retrieved from deceased donors.

Living donation includes donation of tissues (primarily bone marrow), as well as donation of whole organs (eg kidneys) or parts of organs (eg portions of the liver). Currently in Australia, nearly 40 per cent of kidney donations are from living donors — most of these donations are from related donors, though improvements in surgical techniques and immunosuppressive therapies have led to increased rates of unrelated donation. Donation of a portion of the liver is rare in this country, but this procedure, together with donation of a lobe of the lung, is becoming more common overseas. Australia is likely to follow suit. Bone marrow transplantation is well established in Australia from both related and unrelated donors.

Living donation can be either directed or non-directed.

a) **Directed donation** can be to a relative or friend. This is by far the most common type of living organ donation.

b) In **non-directed donation**, donors register on the Australian Bone Marrow Donor Registry or donate a kidney to the general kidney ‘pool’. Donated kidneys are transplanted into the most suitable recipients on the waiting list for deceased donor organs.

Each type of living donation presents a range of ethical issues, principally because of the need to balance the benefits to the recipient against the risks to the donor. The greater the risk of harm to the potential donor, the greater the ethical concern. In addition, emerging issues such as the existence of alternative sources of organs overseas (eg buying and selling of organs, directed unrelated living donation via the Internet) threaten ethical practice.

In light of changes to the Australian Organ Donor Register, the Australian Health Ministers’ Advisory Council requested that the Australian Health Ethics Committee (AHEC) undertake a review of the National Health and Medical Research Council’s *Recommendations for the Donation of Cadaveric Organs and Tissues for Transplantation* (1996). As part of this task, the Working Party appointed by AHEC (see Appendix A) reviewed a discussion paper released by AHEC in 1997, titled *Ethical Issues in Donation of Organs or Tissues by Living Donors*. Submissions from targeted consultations carried out in 2002 and 2005 were also considered.

## SCOPE OF THE GUIDELINES

These guidelines:

a) focus on living donation of organs (particularly kidneys and portions of the liver and lungs) and tissues (primarily bone marrow);

b) outline ethical principles for health professionals involved in donation of these organs and tissues from living donors; and

c) provide guidance on how these principles can be put into practice.

The guidelines *do not*:

a) cover blood donation for transfusion, cord blood donation or donation of reproductive tissues;

b) include information about tissues used for transplantation after removal as part of routine medical care (eg femoral head, live corneas, heart valves, iliac vessels); or

c) deal with the ethical issues involved in the donation of organs and tissues after death (separate guidelines have been developed on this topic), or with mechanisms for increasing community awareness about donation.

It is important that clinicians take account of the relevant legislation in their State or Territory (see Appendix B). Australian legislation is not nationally uniform and individual State and Territory laws may include clauses that are not consistent with some aspects of these guidelines. Clinicians should follow the guidelines except where there is actual conflict between them and their local legislation, in which case the legislation overrides. Where the guidelines apply a higher standard of ethical practice than the legislation, which can be attained while still complying with the specific requirements of the law, the guidelines should be followed. Clinicians are encouraged to bring such disparities to the attention of their local health department and they should then be communicated to the NHMRC.

## STRUCTURE OF THE GUIDELINES

These guidelines provide advice based on a set of principles to guide ethical practice. The following chapters of the guidelines discuss:

a) rates of organ and tissue donation from living donors, presenting a 'snapshot' of the current situation in Australia (Chapter 1);

b) the importance of the informed consent process and how to meet the needs of all those involved in living organ and tissue donation (Chapter 2);

c) practical application of these ethical guidelines by health professionals involved in living organ and tissue donation (Chapter 3);

d) ways in which institutions can support ethical practice (Chapter 4); and

e) discussion of emerging issues here and overseas (Chapter 5).

The appendices include key information sources and the websites of agencies involved in the sector. A booklet for the community has been developed from these guidelines.

# LIVING ORGAN AND TISSUE DONATION — PRINCIPLES

Donation of organs and tissues makes available a relatively scarce resource that has the potential to greatly improve the health and quality of life of recipients.

Respect for humans is a fundamental value involved in medical decisions concerning living donation. It is essential that the decision to donate is voluntary and not coerced, underpinned by a sound understanding of what is at stake, and based on widely endorsed medical criteria. Living donation is often a complex matter and following these principles can require great care. It is particularly important to recognise the pressures to donate that may exist, especially within families.

The notion of avoiding harm is also crucial to medical judgements about whether to accept the wish of an individual to donate tissues or organs. This in turn depends on the organ or tissue to be donated — for example, donating regenerative tissue such as bone marrow involves a lower risk of harm than donating a kidney. It also depends on the emotional factors involved that may make a higher risk more acceptable (for example when parents wish to donate in an attempt to save their child).

To support ethical practice in living organ and tissue donation, it is important that health professionals:

a) assess and take into account the risk of harm to donors and potential benefits to recipients;

b) be sensitive to the rights and interests of patients; and

c) be aware of the social and cultural implications of their decisions.

## Principles embodied in these guidelines

a) Whether the donor and recipient are related or unrelated, living organ and tissue donation is an act of altruism and human solidarity that potentially benefits those in medical need and ultimately society as a whole.

b) Respect for all those involved should be demonstrated through:

   — decision-making processes that ensure that both donors and recipients are fully informed about potential risks and about alternatives to transplantation;

   — ensuring that decisions about donation are free of coercion of any kind including undue emotional pressures or any material incentives such as money or in-kind rewards.

c) In assessing whether to proceed with donation, the autonomy and welfare of the donor take precedence over the needs of the recipient to receive an organ or tissue.

d) Living donation should take place only when there are minimal risks of short and long-term harm to the donor, with no clinically significant loss of a bodily function, and a high likelihood of a successful outcome for the recipient.

e) For those who cannot make informed decisions (for example young children or other dependent persons) to be considered as potential living donors there must be: minimal risks to the donor; no alternative donors available; and the prospective recipient must be a close relative of the child or dependent adult. There must be an independent judgement that the donation is in the overall best interests of the potential donor.

f) Conflicts of interest should be minimised through the use of independent and separate assessment, advice and advocacy for potential donors.

# 1 OVERVIEW

## 1.1 LIVING ORGAN AND TISSUE DONATION

Currently in Australia, most living donations are kidney or bone marrow. However, a range of regenerative and non-regenerative organs and tissues may be donated.

a) *Bone marrow* — bone marrow transplantation, both related and unrelated, is well-established in Australia, and there is a national register of potential bone marrow donors. Bone marrow is removed either through a syringe or by leukapheresis.

b) *Kidney* — surgical removal of a kidney, or nephrectomy, is performed through a standard open procedure or through laparoscopic surgery. The remaining kidney adjusts to perform the functions that both kidneys performed previously.

c) *Liver* — in living liver donation, individuals donate a portion of the liver. The size of the segment and specific part of the liver that is donated depends on the needs of the recipient. Generally, a portion of the left lobe is taken if donating to a child and either the left or right lobe is taken for an adult.

d) *Lung* — living lung donation is a highly complex procedure requiring two donors — one person gives a lobe of their left lung and the other a lobe of their right lung. The two lobes are simultaneously transplanted into a single recipient. The donors' lungs must be the appropriate size and volume. Living lung transplantation is mostly performed in patients with cystic fibrosis who are not expected to survive the waiting time to transplantation with deceased donor lungs.

e) *Other organs and tissues* — less common living donations include a portion of the intestine or the pancreas. Extremely rarely, heart-lung recipients can become living heart donors (called a domino transplant). When a patient receives a heart-lung "bloc" from a deceased donor, his or her healthy heart may be given to someone waiting for a heart transplant. This procedure is used when doctors decide that the deceased donor lungs will function best if they are used in conjunction with the deceased donor heart.

## 1.2 RATES OF LIVING DONATION

The first transplantation using a kidney from a living donor took place in 1954. Since then living donation of kidneys has become increasingly common in Australia and overseas, and living donation of other organs is also increasing. There are two main reasons for the increase in rates of living organ donation, particularly over the last decade:

a) growing demand together with a static number of deceased donors has led to some waiting lists becoming longer, so that living donation is increasingly considered as an alternative source of organs and tissues for transplantation; and

b) with improvements in medical treatments (particularly immunosuppression) leading to better outcomes, living donation and transplantation have become possible for a much wider range of people.

By 2004, the number of living kidney donors in the United States had exceeded that of deceased donors (UNOS 2005).

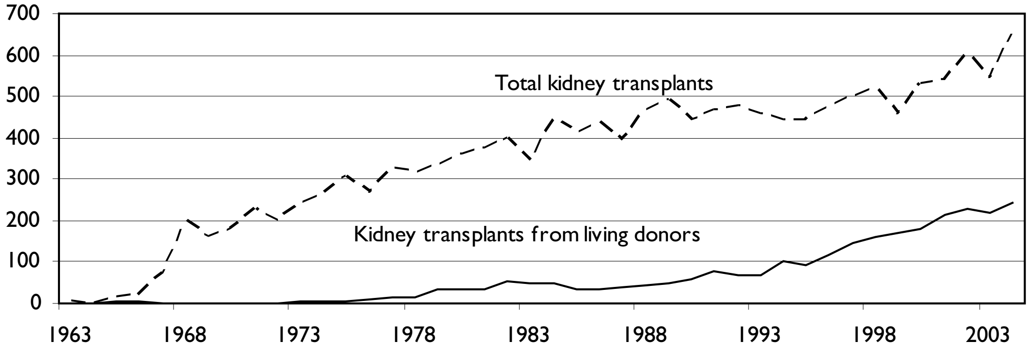
Overseas experience in living donor liver transplantation is rapidly increasing, and lobes of lungs from living donors are also being successfully transplanted.

Bone marrow transplantation, initially using bone marrow from related donors, was pioneered in the 1950s. Advances in HLA matching have since allowed transplantation of unrelated bone marrow. Registers of unrelated bone marrow donors have been established in many countries to provide access to donations for patients unable to find a suitably matched related donor, with over 10 million donors registered worldwide.

### AUSTRALIAN EXPERIENCE

In Australia, kidney transplants from living donors date from the 1960s. In recent years, transplants from living donors have increased at a faster rate than those from deceased donors and thus have increased as a proportion of all donors (Figure 1.1).

**Figure 1.1** Number of renal transplant operations and living donors, Australia 1963–2004



Sources: ANZDATA (2005); Kidney Health Australia 2005.

The proportion of living donor kidney transplants from genetically unrelated donors has increased. This is a major factor in the increasing numbers of living donor transplants (ANZDATA 2004). The proportion of living donor transplants undertaken before the recipient reaches end-stage disease has also increased and now accounts for 25% of all living donor transplantation (ANZDATA 2004).

Living donor liver transplantation remains rare in Australia (only one such transplantation was performed in 2003) (ANZOD 2005). Transplantation of lung lobes from living donors has not yet been undertaken in Australia.

Bone marrow transplants have been carried out in Australia since the 1960s. The Australian Bone Marrow Donor Register, established in 1991, coordinates searches for bone marrow donors. Around 300 new patient searches are carried out each year. As outcomes remain better with related rather than unrelated donors, a family search is carried out before a registry search is initiated. There are currently more than 150,000 registered bone marrow donors in Australia.

## Access to living donation

Living donation may be more accessible to some communities than others, due to cultural and geographical differences. For example, although rates of renal failure among Aboriginal and Torres Strait Islander peoples are much higher than those in non-Indigenous Australians, up to half of all Indigenous patients with end-stage renal disease come from regions without dialysis or transplant facilities (Cass et al 2001). A lack of healthy compatible donors or access to ongoing care also contribute to low rates of transplantation among Indigenous people. Although a living relative often provides the best match, the high rates of kidney disease in some communities may preclude living donations by relatives (AIHW 1999).

# 1.3 OUTCOMES FOLLOWING LIVING DONATION

## DONOR OUTCOMES

### Living kidney donors

Living donor open nephrectomy is associated with complication rates ranging from 4 to 38 per cent with hospital stays of up to 5 days for otherwise healthy volunteer donors (ASERNIP/S 2003). Complication rates for laparoscopic living donor nephrectomy are similar (2 to 31 per cent) but types of complications differ with the method employed — vascular and mechanical complications are more likely following laparoscopic nephrectomy and pulmonary complications, fever, pain and nausea are more common after open nephrectomy (ASERNIP/S 2003).

No large prospective studies have addressed the long-term consequences of nephrectomy for the donor, however a large body of retrospective evidence suggests that there is minimal long-term risk. Studies into outcomes among living kidney donors have found:

a) age-related decline in renal function consistent with that observed in the general population in living donors who had normal renal function at the time of nephrectomy (Fehrman-Ekholm et al 2001) and low probability of serious renal dysfunction (Bia et al 1995);

b) no significant increase in blood pressure and no difference in requirements for antihypertensive treatment (Najaran et al 1992);

c) creatinine clearances or glomerular filtration rates of between 75 and 85 per cent of normal (Grossman et al 2002; David et al 2001; Rizvi et al 2005);

d) subsequent listing for kidney transplantation among a small percentage of living kidney donors (Ellison et al 2002); and

e) a donor death rate of 0.02–0.03 per cent (Matas et al 2003).

There is emerging evidence of psychological morbidity, including depressive, anxiety and adjustment disorders in a proportion of living kidney donors (Smith et al 2004).

The increased demand for kidneys has led to a review of medical contraindications. Conditions such as obesity, and in some cases hypertension or proteinurea, are no longer considered absolute contraindications to donation (Davis & Delmonico 2005; Karpinski *et al* 2006). There is limited understanding of outcomes pending adequate long-term follow up of these donors.

## Living liver donors

A recent systematic review of adult-to-adult liver donor outcomes (Middleton et al 2006) identified the following risks for living liver donors:

a) an overall reported donor mortality rate of 0.2 per cent;

b) potentially lower mortality rate for left lobe donors (0.05–0.21%) than for right lobe donors (0.23–0.5%); and

c) a median donor morbidity rate of 16 per cent, with biliary complications and infections the most commonly reported donor morbidities.

The rate of donor return to work or normal activity was close to 100% at 3 to 6-month follow-up (18 studies). However, the short history of adult-to-adult living donor liver transplantation means that long-term risks for donors are not yet known.

## Living lung donors

Living lung donors experience postoperative pain and occasionally have prolonged air leaks. Serious complications have rarely occurred in living lung donors but most experience around 15 per cent permanent decrease in vital capacity due to loss of the lobe (White-Williams 2002).

## Bone marrow donors

Donation of hematopoietic stem cells through bone marrow is a generally safe procedure for healthy donors. Serious adverse events are uncommon and death is exceedingly rare (Horowitz & Confer 2005).

# RECIPIENT OUTCOMES

## Living donor kidney recipients

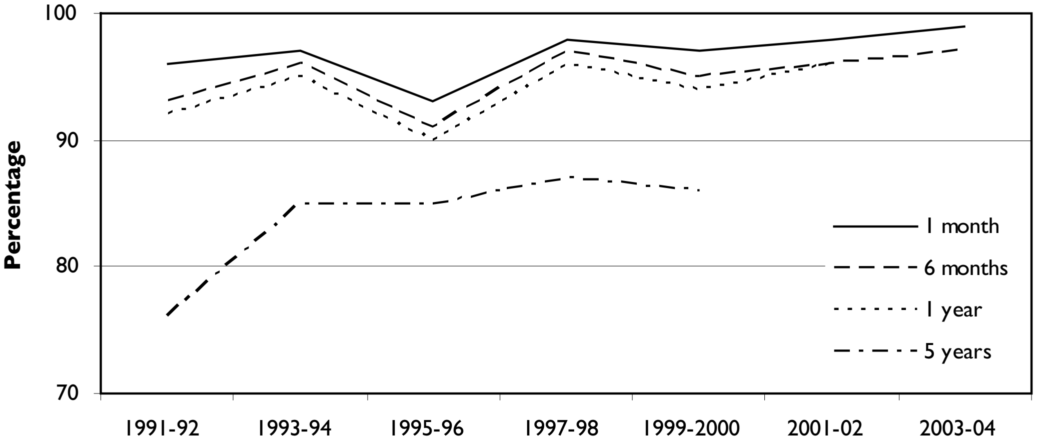
Living donor kidney transplantation provides patients in end-stage renal disease with the best chance of long-term survival. Evidence suggests that there is improved graft survival in transplants performed pre-emptively, making it the treatment of choice (British Transplantation Society & The Renal Association 2005). Planned transplantation, before dialysis becomes inevitable, is an attractive option for patients.

Of the kidney transplants performed in Australia since 1963, living donor transplants accounted for 17% of operations and 28% of functioning grafts. The number of functioning grafts from living donors increased by 11% from 2002 to 2003 (ANZDATA 2004).

Graft survival rates from unrelated donors are comparable to those of living related donors and are superior to deceased donor kidney grafts (Terasaki et al 1995; Cecka 2000; Gjertson and Cecka 2000; Humar et al 2000).

Indigenous Australians, especially those from remote regions, have worse outcomes than non-Indigenous people after renal transplantation, probably because of higher rates of comorbidity, especially Syndrome X disorders (insulin resistance, associated obesity and hyperlipidaemia) (Spencer et al 1998).

**Figure 1.2** **Graft survival following living donor kidney transplant, Australia 1991 to 2004**



Source: ANZDATA Registry (2004).

The pattern of long-term complications for recipients of living donor kidney transplantation is changing, for two main reasons:

a) there is less dependence on tissue matching between donor and recipient such that growing numbers of living donor kidney recipients receive less well matched grafts, which in some cases will lead to the use of more intensive immunosuppression with the greater chance of long-term complications; and

b) overall rates of rejection, organ loss and infection have decreased, making cardiovascular disease and cancer the greatest risks to long-term graft and patient survival among transplant recipients. Efforts are underway to identify and minimise risk factors for cancer and cardiovascular disease in transplant patients (Buell et al 2005; Holdaas et al 2005; Meier-Kriesche et al 2003).

## Living donor liver recipients

On average, one in eight adult living donor liver transplantation recipients dies within months of transplantation, a similar proportion to that seen for adult recipients of deceased donor liver transplantation (ASERNIP/S 2004). Long-term survival rates after living donor liver transplantation are not known, but would be expected to follow patterns seen for deceased donor liver transplantation (ASERNIP/S 2004), in which 18-year survival has been reported to be 44 per cent (Jain et al 2000). Causes of death following living donor liver transplantation include infection, liver and multiple organ failure, and recurrent disease (ASERNIP/S 2004).

Generally, rates of complications and other outcomes for adult patients receiving transplanted livers from living donors are similar to those receiving livers from deceased donors. However, rates of biliary complications are higher following transplantation of a living donor liver (Lui et al 2006).

## Living donor lung recipients

Although data are limited, it appears that recipient outcomes and rejection rates for living lung transplantation are comparable with those for recipients of deceased lung transplants (White-Williams 2002).

## Bone marrow recipients

Bone marrow transplantation is used to treat a wide range of malignant and non-malignant conditions. Outcomes from the treatment vary depending on patient factors, including the condition being treated.

## 1.4 CURRENT AND EMERGING ETHICAL ISSUES

The ethics of living donation differ from those of deceased donation because the treatment affects not only the recipient but also the healthy person who volunteers to donate. Living donation appears to contradict the fundamental ethical principle of non-maleficence ('do no harm'), as healthy individuals undergo medical interventions that are not for their physical benefit and may cause lasting physical damage. The autonomy of the potential donor (reflected in his or her free and informed decision about donation) has to be balanced carefully against the possible physical and psychological risks. These risks will be different in every case – the important ethical consideration is that donation may only proceed if donors understand and accept the risk to themselves, and the health professionals involved consider the donation to be based on sound medical criteria. The welfare and interests of the donor always should take precedence over the medical needs of the potential recipient (British Transplantation Society & The Renal Association 2005). This is discussed further in Chapter 2. In the case of young children or dependent adults who cannot make a decision for themselves, there needs to be an independent judgment that donating would be in their best interests (see Section 2.3).

The rapidly evolving culture of transplantation contributes to the complex ethics of living donation. Living organ and tissue donation and transplantation are constantly changing, in both medical and social terms. Ethical guidance needs to reflect long-standing principles, which have to be re-examined to encompass new technologies. Important issues include:

a) the rapid increase in acceptance of marginal donors (ie those with co-morbidities that would previously have precluded them from donating), which presents practical and ethical challenges for many transplant units;

b) non-directed kidney donation, which requires intense and time consuming screening of those offering to donate a kidney to a stranger;

c) some newer forms of living donation, such as paired donation and list exchange, which are practiced overseas. These kinds of donations are rare or not yet practiced in Australia. Community ethical debate and legal consideration are required prior to any decisions about their acceptability; and

d) controversial emerging practices (eg internet matching, buying and selling of organs), which are ethically unacceptable and also illegal in Australia.

Marginal donors and non-directed donation are discussed briefly below. Newer and more controversial ethical issues are discussed in Chapter 5, with the aim of highlighting these matters for further community and professional discussion.

## MARGINAL DONORS

Increasingly, it is possible for living donors to have co-morbidities or some degree of immunological incompatibility with the recipient, because previous barriers associated with medical suitability and tissue-matching have been largely overcome. In order to meet standards for informed consent, potential marginal donors should be advised about their likely increased risks and the lack of data on long-term outcomes relevant to their situation. Assessment of the medical risks for marginal donors is made more difficult by this lack of data. There is need for rigorous follow-up of marginal donors so that outcome data can be collected to inform future practice. Recipients of a non-matched donation may be at increased risk of complications and should be advised of the implications of transplantation involving a marginal donor.

## NON-DIRECTED DONATION

Non-directed donation of bone marrow is well established — this tissue is collected from registered volunteers and allocated to individuals unknown to the donor, according to need. Non-directed (or "good Samaritan") kidney donation also occurs, although it is uncommon in Australia. It can happen when altruistic individuals approach transplant centres seeking to donate a kidney to a person in need of a kidney transplant. The donor has no involvement in deciding who will receive the kidney — it is allocated through standard procedures to the most appropriate patient on the existing list waiting for a deceased donor transplant.

Non-directed kidney donation is ethical only if there is no active recruitment of donors, and no financial or other incentive for the donor to donate a kidney (apart from the wish to do good). The motivations of potential donors can be extremely difficult to determine. It is very important that ethically sound and transparent principles of allocation are used for organs donated in this way.

The ethical implications of non-directed donation are discussed further in Chapters 2 and 3.

# 2 ETHICAL PRACTICE

Ethical practice in the area of living organ and tissue donation and transplantation is based on the principles given on page 5 of these guidelines. This chapter expands on these principles.

The key to ethical practice in living donation is supporting free and informed decision-making, so that the donor can make an independent decision.
This involves:

a) understanding individual situations and the complex pressures and motives that may affect decision-making about living donation within families (Section 2.1);

b) providing information and support during the decision-making process (Section 2.2); and

c) considering the additional ethical complexities involved in decision-making on behalf of children and dependent adults (Section 2.3).

Health professionals have an important role in considering the balance of risks in each case and ensuring that donation happens within safe limits (Section 2.4), and in preserving the well-being of themselves and other staff members (Section 2.5).

## FURTHER INFORMATION

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

a) Making a Decision about Living Organ and Tissue Donation — 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 B); and

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

## 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 B.

## Checklist for ethical practice

### Understanding the situation

- Be aware that decision-making in living donation can be highly charged and requires careful and sensitive handling, especially in situations where a potential donor's main motive is to help a loved one.
- Consider the complexities of the relationships involved as these may affect the extent to which a decision whether or not to donate is genuinely voluntary.
- Ensure family and/or individual counselling is available to assist potential donors to come to a well-considered decision.

### Supporting informed decision-making

- 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.
- Wherever possible, ensure sufficient time and care can be taken to allow informed decision-making.
- Involve Aboriginal Health Workers or Aboriginal Hospital Liaison Officers when communicating with Aboriginal and Torres Strait Islander people.
- Use culturally appropriate materials and the services of trained translators when providing information to people from culturally and linguistically diverse backgrounds.

### Making a decision on behalf of a child or dependent adult

- Ensure the family understands that the decision-making process requires an independent assessment of the child or dependent person's best interests in relation to donation.

### Professional responsibility in decision-making

- Take all reasonable steps to establish that donation is altruistic and that no element of coercion or commerce is involved.
- Consider the balance of risks in each case and ensure that donation occurs within safe limits.
- In non-directed donation,ensure high levels of confidentiality for both donor and recipient.

### 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 UNDERSTANDING THE SITUATION

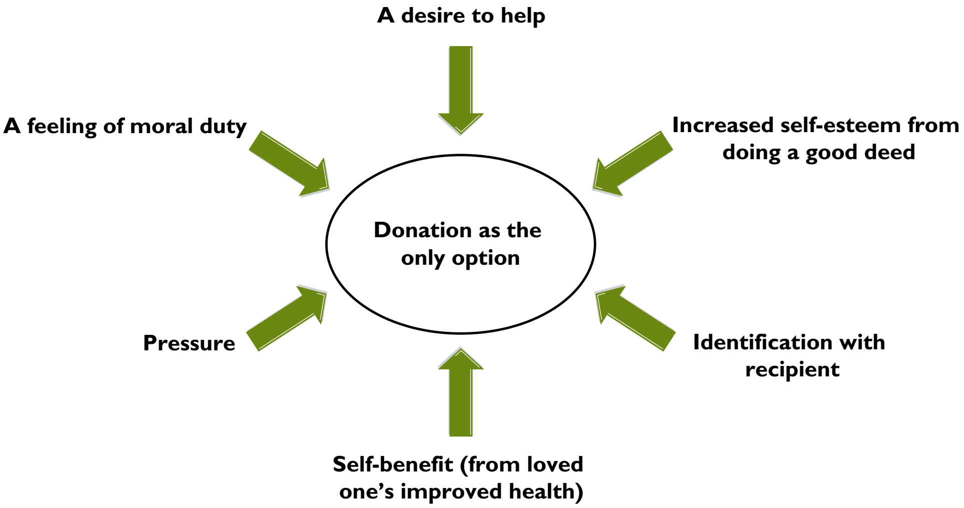
Before information can be given to enable informed decision-making, health professionals need to have some understanding of the particular situation and the individuals involved. While living donation can be positive for all concerned, the circumstances often mean that the experience is intense and emotional, and needs to be handled with care and sensitivity. Health professionals are required to ensure that the donation is altruistic — there must be no element of coercion associated with living donation and no expectation of the donor receiving financial or in-kind rewards or material benefits as compensation.

### DIRECTED DONATION

Most donations occur within families or other close relationships, with donor and recipient either genetically or emotionally related. The pressures on potential donors can make their decisions highly charged. It may be that the intended recipient will die without the transplant, or will have to continue to undergo dialysis or other invasive treatment long term. The nature and urgency of the situation may lead the donor to assume there is no choice but to agree. Health professionals need to consider the complexities of the relationships involved as these may affect the extent to which a decision to donate or not to donate is genuinely voluntary.

Understanding the motives of living donors and the decision-making process can assist in assessing the situation. A Swedish study identified categories of motives that lead the potential donor to a decision that donation is the only option (see Figure 2.1) (Lennerling et al 2003).

**Figure 2.1 Motives involved in becoming a living donor**



Source: Adapted from Lennerling et al (2003).

Most of these motives are likely to result in a positive psychological outcome for the donor. However, situations where a potential donor's main motive is pressure to donate to a loved one or friend need to be handled very carefully. This pressure can come from within the family, so that a person who is the best match with the recipient may feel coerced into agreeing (eg a young woman's parents putting pressure on her to donate a kidney to her sick brother). Even when there is more than one suitable donor, there can be complex pressures as a choice is made between these people. In other cases there may be one person who is extremely eager to donate and perhaps too willing to overlook possible difficulties (eg parents insisting on donating to try to save the life of their child).

Some people may feel coerced if an approach about donation comes from a health professional, where others may feel overwhelmed by the intrinsic emotional pressure of being asked directly by the potential recipient. For this reason, donation should be raised by the person who is least likely to make the potential donor feel under pressure.

Some people may be able to make a voluntary decision despite these pressures. In other cases, potential donors cannot decide for themselves, but give in to the strongest influence. This situation should be avoided as it may cause lasting harm to the donor and to relationships in that family. Careful counselling and well-structured situations may be needed to assist a person to sort out the issues sufficiently so that he or she can come to a well-considered decision.

The context of the decision will play a part in the decision-making process. For example, the decision to donate is immediate for most parents, but is often more difficult and complex for siblings (Franklin & Crombie 2003). In any situation, this process may be facilitated by individual and/or family counselling. Whatever the decision of individuals about whether or not to become living donors, they may still need to talk to a counsellor or other independent adviser throughout the decision-making process and afterwards. Even in emergency situations (eg when the intended recipient will die if the transplant does not take place quickly), it is important for the future well-being of donors that they are supported through the decision-making process (discussed further in Chapter 3).

The Australian and New Zealand Society of Nephrology/Kidney Health Australia guidelines recommend that adequate provision should be made for ensuring that a donor can withdraw from a donation or honourably withhold donation. It is important that potential donors are made aware that if they do not want to donate or they change their minds, their reasons for not proceeding will be kept confidential.

There may also be pressure on recipients to accept a donation from a living donor. Recipients should be made aware as part of the consent process that they are free to refuse a donation from a known donor (eg a parent in need of a kidney transplant may not want his or her child to go through the donation process). Refusal of living donation (either directed or non-directed) should not prejudice that person's chance of subsequently receiving organs or tissues from a deceased donor.

## NON-DIRECTED DONATION

For potential donors who wish to make a donation outside a family context, for example an individual deciding whether or not to donate bone marrow or a kidney to an unrelated stranger, there are many complex issues to consider. Choosing to donate a tissue such as bone marrow for the benefit of a stranger is relatively simple as the donor is highly unlikely to suffer lasting harm and any inconvenience will be temporary. However, the wish to donate a kidney to the general pool needs to be assessed carefully as the decision may be based on potentially harmful motives (eg depression, desire for attention).

Health professionals have a responsibility to investigate a person's reasons for wishing to donate a kidney and to identify any that may be unrealistic or harmful. Non-directed altruistic kidney donors are accepted only after an intensive psychological screening process to assess their motivation, suitability and consent, and after they are given information about the risks to themselves and the recipient. There should be a cooling off period of several months after this process to allow donors to think it all through very carefully.

It is also important that potential recipients are informed that an allocated organ may be from a non-directed living donor, and made aware that they can refuse this offer without prejudicing their chances of receiving an organ from a deceased donor.

Anonymity between donor and recipient should be maintained, to avoid possible future repercussions for either party. Despite the intense screening process that assesses a donor's motivation, some donors may develop feelings of ownership and if their recipients are known to them, may develop inappropriate expectations (eg seek to gain financially or emotionally). Although health professionals are bound to preserve the confidentiality of patients, in some situations, anonymity is very difficult to maintain. For example, the donor and recipient may be cared for in the same hospital, and living donation often attracts publicity and speculation. In the case of domino transplantation, both patients are usually cared for in the same unit. Recipients should be informed of the risk of being identified and given counselling if necessary.

It is important that staff are aware of the need for confidentiality, and the importance of individual sensitivity and vigilance in this regard. Approaches by the media should be handled by those responsible for hospital public relations rather than individual health professionals.

The Transplantation Society of Australia and New Zealand (TSANZ) and NSW Health have both issued guidelines on non-directed living donation (see Appendix B).

## 2.2 SUPPORTING INFORMED DECISION-MAKING

Potential donors, recipients and their families need a range of information that is relevant to their circumstances, given in a manner that is appropriate to their understanding and experience.

### PROVIDING INFORMATION

In any situation where medical treatment is being considered, patients or their representatives have a right to make their own decisions, and a right to grant, withhold or withdraw consent before or during examination or treatment (NHMRC 2004b). To do this, they need adequate information about the condition and any proposed investigations, procedures, treatments and material risks.[1] Health professionals have a duty of care to assist people in gaining an understanding of the possible consequences, both positive and negative, of any decision they make (NHMRC 2006; see Appendix B).

Individuals and families should be given the opportunity to ask relevant questions and to have their questions answered in a sympathetic environment. Information should be provided in a manner that is suitable to their understanding and reinforced with written materials. The language used should be simple and free of medical terminology and the health professional should try to ensure that the information is understood and retained (NHMRC 2004b and 2004c; see Appendix B).

More specific advice on the information that should be provided to potential donors and recipients is given in Section 3.2.

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[1] Material risks are those that most people would want to know and also those that would be significant for a particular individual (eg side effects, possible outcomes).

## Cultural issues

Cultural differences can have an impact on the process of informed decision-making. Independent, trained medical translators (not family members acting as translators), and translated information and consent forms should be used for people from a non-English speaking background. Discussion should take place in a culturally safe and appropriate environment.

Even where language is not an issue, health professionals should be aware that:

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

b) a person's understanding may reflect lack of information about the medical situation, but there may also be cultural and spiritual differences that affect acceptance of living donation. Underlying these cultural differences is a wide range of factors, including diverse views about bodily integrity.

Organ and tissue donation and transplantation may be incompatible with the traditional beliefs of some Aboriginal and Torres Strait Islander people. Whether or not the patient holds traditional beliefs, health professionals are ethically obliged to inform Aboriginal and Torres Strait Islander patients of the possibilities presented to them by donation and transplantation. As with all members of the community, Indigenous patients should be given advice in a respectful and non-coercive fashion. The ultimate decision about donation and transplantation rests with the individual. The involvement of an Aboriginal Hospital Liaison Officer and/or Indigenous health worker will help to ensure that communication takes place in a culturally appropriate way.

## PROVIDING SUPPORT

The donor and recipient may or may not be treated by different doctors. In the case of living related donation, it is probable and practical that the potential donor will first discuss donation with the recipient's doctor as it is likely that the family of the recipient will have an ongoing relationship with that doctor. Because the recipient's doctor usually has had a long-term commitment to the recipient, it is mandatory that the potential donor have at least one assessment by a health professional who is not involved in care of the recipient and who can act as an independent advocate to protect the donor's interests (this is discussed further in Chapter 3).

All unrelated bone marrow donors are treated by a doctor who is not involved in treating the potential recipient. However, in Australia there are no standard procedures for separate treatment for donors and recipients involved in other types of organ and tissue donation.

There are several medical, psychological and social considerations that shape decision-making in the context of a particular family, or for a particular individual. These are outlined in Chapter 3 and need to be discussed in every case.

**Rights of potential donors:**

a) the right to medical information about the donation procedure and its short-term risks as well as information about the long-term risks of the donation;

b) the right to information about the recipient's medical prospects following transplantation;

c) the right to independent medical advice;

d) the right to counselling to discuss the potential psychological and social consequences of the decision to donate and adequate time to consider this information; and

e) the right to decide not to donate and to receive counselling following such a decision.

## 2.3 DECISION-MAKING ON BEHALF OF A CHILD OR DEPENDENT ADULT

Donation by children or dependent adults is ethically complex. For this type of donation to be ethically acceptable, there must be: minimal risks to the donor; no alternative donors available; and the prospective recipient must be a close relative of the child or dependent adult. The decision-making process requires an independent assessment of the child or dependent person's best interests in relation to donation.

The same basic principles apply to donation by dependent adults and children because consent to donation is given by others, such as a child's parents or an adult's guardian or legal decision-maker.

## CHILDREN

A child may be sought as a donor to a sibling or a parent, particularly for bone marrow donation. Living donation of regenerative tissue by children is legally permitted, under certain strict conditions, in all Australian States except the Northern Territory. However, living donation by children of non-regenerative tissue is permitted only in the ACT and then only under the most exceptional circumstances and in relation to certain classes of recipients. Every child has the right to bodily integrity irrespective of the needs of others. A living child's body or body parts should never be seen as a resource for another person.

The fact that a child may be the only suitable bone marrow donor for a sibling or parent raises a number of ethical considerations:

a) because of their immaturity and dependence, children are very vulnerable and great care needs to be taken to protect their interests;

b) it is difficult and, in cases of very young children, impossible to ensure that children have an adequate understanding of what is involved; and

c) where one child is being considered as a donor for another, parents face the issue of trying to juggle the potential harms of intrusive procedures and risks for the donor child against the potential benefits to his or her sibling.

However, the possible death of a sibling or parent may be such a serious threat to the well-being of potential donors that their overall interests would be more damaged by his or her relative's death than by the discomforts of bone marrow donation. In that case, becoming a donor may be in the best interests of the donor child and thus justify performing a non-therapeutic procedure on that child.

### Communication and understanding

The child's understanding of donation and transplantation may be incomplete, but efforts are required to ensure that his or her understanding is as thorough as possible, consistent with age. As children mature, they will be able to have a better understanding of such matters and a clearer appreciation of the significance of their own decisions. Therefore, although legally still minors, older children should be encouraged to take a more active part in such decision-making than younger children.

Children who are to be recipients of transplants should also be informed and involved. The opinions of the potential donor and recipient child should both be taken into consideration in the decision-making process, and a considered refusal by either child should be respected.

## DEPENDENT ADULTS

Dependent adults are adults who have impaired decision-making capacity due to a psychiatric illness or disability, intellectual disability, acquired brain injury, or some form of dementia.

When a dependent adult is identified as a potential donor, similar ethical issues arise as those outlined for children:

a) it may be difficult to ensure that the potential donor has an adequate understanding of what is involved in donation and transplantation and the implications for their own health or for that of the recipient; and

b) there may be a conflict of interests if the person's legally appointed decision-maker has a relationship with both the potential donor and the recipient.

It is therefore important that:

a) efforts are made to ensure that the person's understanding is as thorough as possible, consistent with his or her mental capacity; and

b) an independent assessment is carried out to ensure that the donor's best interests are not compromised.

## PROCESS OF INDEPENDENT JUDGEMENT

Parents or other legally appointed decision makers may be in a situation of conflict if they need to consent on behalf of both donor and recipient. A process of independent judgement (see page 32) is required to determine, on a case-by-case basis, the potential donor's best interests and whether or not the donation should go ahead. This judgement should involve medical, psychological, social, legal and ethical expertise.[2] This process is outlined in more detail in Chapter 3.

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[2] As the peripheral blood of young children is rich in stem cells, it is sometimes possible for stem cells for donation to be collected from their blood rather than bone marrow. This type of donation is less invasive and does not require the assessment and review process outlined here. However, the medical officer must be satisfied that the volume of blood collected does not pose any health risk to the donating child and the consent of the parent or guardian is still required for donation. If clinical intervention such as bone marrow stimulation is contemplated, the processes outlined for donation from children should be followed.

### Ethical decision-making on behalf of children and dependent adults

Decisions to permit a child or dependent adult to be a living donor will be ethically acceptable only where:

a) the risks and discomforts to the donor are minimal and the tissue is regenerative;

b) the donation is to a person with whom the donor has an intimate or ongoing relationship (ie a close relative);

c) the donation is a last resort in treatment for the recipient;

d) there are no alternative donors;

e) the proposed transplant is of proven efficacy and of great expected benefit to the recipient;

f) there is an independent judgement that the donation is in the donor's overall best interests;

g) the parents or guardians consent and the child or dependent adult (if she or he is able to do so) agrees or assents; and

h) where required by law, a Court or tribunal authorisation has been obtained to undertake a non-therapeutic procedure on a child or dependent adult on the basis that the procedure is in his or her interests.

## 2.4 PROFESSIONAL RESPONSIBILITY IN DECISION-MAKING

As well as ensuring that the donor is properly informed and consent has been freely given as discussed above, health professionals are obliged to ensure that a proposed donation meets sound medical criteria. This involves considering the balance of risks in each case and ensuring that donation happens within safe limits.

Donation of non-regenerative tissue by a competent adult is considered ethically acceptable when the risks of long-term harm are minimal and the removal involves no loss of functional integrity — for example, allowing kidney donation by a person who is well and will retain adequate renal function through the remaining kidney.

However, this area is becoming more complex with the trend toward accepting donors who are at increased risk following donation because of conditions such as adult onset diabetes, hypertension or a family history of disease that predisposes them to a loss of function following donation. Some newer types of organ donation, such as partial liver or lung lobe, also involve greater risks than those of kidney donation and the various types of tissue donation.

It can be challenging for health professionals to meet their responsibility to ensure that the proposed donation meets sound medical criteria. The potential for donation to save another's life or improve his or her health may lead well-motivated people to take excessive risks, especially if they have a deep emotional attachment and sense of responsibility (eg a parent for a child).

Health professionals are directly responsible for their interventions in the bodies of patients, and for ensuring that exercising professional skills and abilities is not the cause of harms to patients.

### Ethical considerations

Health professionals should consider the following in assessing whether or not living donation should proceed:

a) the expected benefits to the recipient must outweigh the risks associated with donation and there should not be more than a low probability of serious harm to the donor, including serious psychological harm; and

b) donation of non-regenerative tissue should occur only where this will not impair function, be detrimental to the donor's quality of life, or involve serious danger to the donor's life.

Elements of the assessment that support ethical practice are given in Chapter 3.

## 2.5 PRESERVING WELL-BEING OF HEALTH PROFESSIONALS

A range of health professionals is likely to be involved in the process of living organ and tissue donation. These professionals have an obligation to preserve their own well-being and to pay attention to the impact on their colleagues of being involved in living donations.

While often very rewarding, caring for living organ and tissue donors, recipients and their families is intense and can cause personal stress to the health professionals involved. Institutional support for staff members involved in living organ and tissue donation is discussed in Section 4.2.

## SUPPORTING HEALTH PROFESSIONALS

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

a) Employers are obliged to provide a supportive environment that recognises and validates responses to difficult and stressful situations and facilitates recovery. Should involvement in living organ and tissue donation have an effect on well-being, health professionals should seek assistance (eg counselling, debriefing) through their institution.

b) While an individual health professional must 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 or abandonment, or undermine confidence in others who have chosen to participate in a widely accepted professional activity such as organ donation.

# 3 IMPLICATIONS FOR CLINICAL PRACTICE

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

a) psychological, social and medical assessment to ensure the suitability, safety and well-being of both the donor and recipient (Section 3.1);

b) involvement of the donor, recipient and transplant team in the decision-making process (Section 3.2); and

c) ongoing medical and psychological care of donors (Section 3.3).

## CLINICAL GUIDANCE

Guidelines on clinical considerations have been developed by a number of organisations, including the Transplantation Society of Australia and New Zealand (TSANZ), Australian and New Zealand Society of Nephrology/Australian Kidney Foundation, the Australasian Transplant Coordinators' Association (ATCA) and the Australian Bone Marrow Donor Registry (ABMDR). These are listed in Appendix B. These documents should be consulted where appropriate.

## LEGAL GUIDANCE

Health professionals are required to work within the legislation of the State or Territory in which they practise. Links to relevant legislation are given in Appendix B.

## Checklist for ethical practice

### The evaluation process

- Inform prospective donors about the purpose of the evaluation, the type of investigations that will take place, and the health professionals who will be involved.
- Conduct the evaluation in a logical sequence so that invasive procedures are carried out only after non-invasive procedures and psychological and social assessments indicate that there is reasonable certainty that donation will proceed.
- Ensure that every potential living donor is assessed at least once in confidence by a health professional independent of the transplant team, who may then act as the donor's advocate.
- If involved in assessing a potential donor, provide a written evaluation of the person's suitability as a donor to the health professional nominated as that person's independent advocate.

### Decision-making

- Provide potential donors with the information necessary for them to make a fully informed decision.
- Take all reasonable steps to ensure that the time available for decision-making is used as effectively as possible.
- Inform potential donors that they have the opportunity not to proceed with donation and that reasons for non-donation will remain confidential.
- Ensure that the processes of donor and recipient decision-making and consent follow institutional protocols and are clearly documented.

### Ongoing care of donors

- Make arrangements for continuing medical and psychological follow-up of living donors
- If a donor is identified as unsuitable, be sensitive in communicating why this is so and make arrangements for appropriate care or referral.
- If communicating poor outcomes of transplantation to the donor, be sensitive to the time, place and manner in which the information is given.

## 3.1 THE EVALUATION PROCESS

Evaluation for living donation depends on the organ or tissue to be donated. Psychological, social and medical assessments are essential to ensure the suitability, safety and well-being of both the donor and recipient. Potential living donors should be assessed at least once in confidence by a health professional independent of the transplant team, who may then act as the donor's advocate.

Assessment of children or dependent adults as potential donors should be carried out by a team that is independent of the transplant team and has medical, psychological, social, legal and ethical expertise. Reports by these professionals should then be considered by an independent advocate for the potential donor.

The assessment and consent process for living organ donation is complex and, unless there is an urgent need for transplantation, may take a number of months. The health professionals conducting the assessment will vary between settings and types of donation. Even in emergency situations, the living donor evaluation process involves:

a) psychological assessment with the aims of preventing psychological harm to the prospective donor and ensuring that donors are fully informed and making their decision about donation without coercion;

b) social assessment to ensure that the donation would not have an unreasonable negative impact on the donor's social or financial well-being; and

c) medical assessment to consider the suitability of the donor organ for transplantation to the recipient (anatomy, function and risk of transmittable disease) and identify contraindications and unreasonable medical risks for the donor, following established guidelines or protocols.

Assessment of potential bone marrow donors is likely to be less complex as there are fewer risks and normal activities can be resumed soon after the donation procedure. However, the ethical requirements for donor assessment remain, particularly when the potential donor is a child or dependent adult.

### CONSENT TO THE EVALUATION

Before assessments to identify suitability for donation are carried out, prospective donors (or their representatives in the case of children or dependent adults) should be provided with information about the purpose of the evaluation, the type of investigations that are to take place, and the health professionals who will be involved.

Once consent to proceed with the evaluation has been given (as per institutional protocol), the evaluation should be undertaken in a logical sequence so that invasive procedures, such as a biopsy or angiography, are carried out after non-invasive procedures and psychological and social assessments, and only if there is a reasonable certainty that donation will proceed.

The evaluation process is the same whether the proposed donation is directed or non-directed.

## PSYCHOLOGICAL ASSESSMENT

Because of the sensitive issues involved and the need for a comprehensive psychological assessment, this part of the evaluation should be carried out by a health professional who:

a) has appropriate training and experience in mental health (eg psychiatrist, psychologist, clinical social worker);

w) is experienced in the psychology of transplantation; and

c) may be a member of the medical team responsible for donor evaluations or an external consultant to the team.

If the potential donor is a child or dependent adult, the health professional must have experience in assessing a child's understanding, based on age, maturity, emotional readiness and mental capacity. Where appropriately experienced professionals are not available within the hospital, networks should be in place to facilitate referral.

Psychological assessment of the potential donor should include some discussion with the potential donor's partner and/or family. Refusal by the donor to give permission for this involvement may suggest coercion or that the donor is going against the wishes of the family. While it is the individual's right to make such a decision, it is important that the assessor sees first hand the reaction of the others close to the potential donor. Additionally, there is the issue of whether there are other potential demands on the donor's organs and tissues. This is particularly relevant where there is a genetically determined disease.

Where the psychological assessment suggests that the relationship between the donor and recipient may involve an imbalance of power — such as where the prospective donor is an employee or in a dependent relationship with the recipient or where cultural influences may affect decision-making — special attention needs to be given to ascertaining the nature of the relationship and possible motivations to donate.

**Core components of pre-donation psychological assessment of living donors:**

a) reasons for donation;

b) relationship between donor and recipient;

c) attitudes of significant others toward the donation;

d) psychological health history and current status; and

e) education about mental health outcomes following donation.

## Non-directed donors

As with assessment of potential directed donors, psychological assessment of prospective non-directed living organ donors is an evolving process, requiring more than one assessment and a cooling-off period of up to several months.

A person should never be accepted as a non-directed living donor if psychological assessment indicates that his or her decision is likely to be influenced by psychological ill-health.

If any mental health conditions are identified through the psychological assessment, the donor should be referred to appropriate mental health services.

## SOCIAL ASSESSMENT

Assessment of potential short and long-term social consequences of donation should be carried out by the hospital social worker, with family involvement.

**Core components of pre-donation social assessment of living donors:**

a) living arrangements;

b) work-related issues; and

c) financial issues.

## MEDICAL ASSESSMENT

Medical assessment should be conducted by health professionals who have experience and qualifications appropriate to the type of donation proposed and, in the case of non-directed donation, who are not involved in the care of the recipient. The potential donor should have at least one confidential consultation with the health care professional doing the medical assessment, and if appropriate, this person should play a key role in continuing care should the donation proceed.

Medical assessment of the prospective donor should be conducted in line with relevant guidelines (see Appendix B) and local protocols (see Chapter 4).

## DOCUMENTING AND CONSIDERING FINDINGS OF THE EVALUATION

Following the assessments outlined above, a written report on each aspect of the evaluation should be provided by suitably qualified health professionals. The report should specify whether or not the following pre-conditions for donation are met:

a) the potential donor is competent to make such a decision and has made it voluntarily; and

b) no significant psychological, social or physical harm is likely to be associated with the donation.

The report should then be considered by the health care professional who is the independent advocate for the donor and any other professionals or committees, as per institutional protocols. If there are no contra-indications to donation, decision-making by the transplant team and formal processes for consent may proceed.

### Additional considerations in evaluating children and dependent adults

For children and dependent adults, reports from ethical and legal experts are required in addition to reports of psychological, social and medical assessments. These reports should outline any ethical or legal impediments to donation.

The advice provided in all of these reports should be considered and weighed by a person or committee separate from the transplant team (as per institutional protocol) who then provide a decision on whether the donation is in the best interests of the child or dependent adult. If the donation is approved by this committee, decision-making by the transplant team and formal processes for consent may proceed.

## 3.2 DECISION-MAKING

Adequate time should be allowed whenever possible for the donor, recipient and assessment team to agree on whether to proceed with donation.
There is no obligation on the transplant team to proceed where they believe the potential risks may outweigh the benefits. The donor and recipient are also free to withdraw from the process.

### TRANSPLANT TEAM DECISION ON DONOR SUITABILITY

Medical and psychological assessments assist the donor in making a decision and provide the health care team with information to support any donor decision on whether to proceed. The transplant team responsible for accepting a potential donor for surgery should base their decision on whether:

a) the psychological assessment suggests that there may be coercion, ambivalence or the potential for adverse emotional effects after the donation, or insufficiently informed decision-making;
b) the donor is biologically incompatible with the recipient (eg blood, tissue or crossmatch).
c) there are medical or surgical contraindications (eg pregnancy, malignancy, obesity); or
d) there is the potential for infection of the recipient (eg HIV).

The team should also ensure that arrangements for medical and psychological follow-up after donation are in place as a condition of suitability.

Even if other members of the team are in agreement about the donation proceeding, the surgeon has a right to refuse to proceed based on an assessment of risk.

In cases where the team decides that the potential donor is unsuitable due to medical or surgical contraindications, the potential donor may choose to seek a second opinion elsewhere. The same process of assessment must be carried out at the institution where this second opinion is sought.

## DONOR DECISION-MAKING

Health professionals can play a role in supporting donor decision-making by providing information (see Section 2.2) but should not exert any influence over the decision-making process.

Time is needed to ensure adequate disclosure and understanding of donation, its risks and benefits. The process of decision-making may take some time and in some cases a two-step or multi-step process of consent may be needed. Unless the potential recipient is very ill and death is imminent, the potential donor should be given a cooling off period between giving consent and the donation operation to allow ample time to confirm the decision.

In emergency situations where there are high immediate risks to the recipient (eg fulminant hepatic failure), this process is, by necessity, accelerated and time for reflection is limited. Every effort should be made to ensure that the time available for decision-making is used as effectively as possible so that potential donors make the best possible decision in the circumstances.

All potential donors should be given the opportunity not to proceed with the donation for any or no reason. In particular, directed donors must be able to decline without disclosure of the reason for non-donation to the recipient, their family or others close to the recipient.

**Information provided to potential donors should include explanation of:**

a) the surgical procedure, recovery and recuperation, the risks of surgical complications and the potential for long-term medical complications;

b) the potential for psychological effects both immediately after the donation and in the longer term (eg depression, guilt, relationship problems) and risk factors that make these more likely (eg past or current mental health conditions);

c) possible changes to the donor/recipient relationship in directed donation (eg feelings of "ownership" towards the recipient by the donor or of intense gratitude by the recipient);

d) the specific risks and benefits to the potential recipient, and the possibility of graft failure or death of the recipient;

e) the availability of ongoing medical and psychological support for the donor;

f) any other information that may affect the donor's decision (eg potential bone marrow donors should be told that there may be a request for a second donation); and

g) any uncertainty about the implications of donation on their ability to work and to obtain health and life insurance in the future.

## Documenting consent for adults

For living donation by an adult to proceed, the donor must give written consent and the independent advocate for the donor must certify that:

a) the donor's written consent was given in his or her presence;

b) the donor received explanations about the nature and effect of the removal of the organ or tissue from his or her body; and

c) the responsible medical member of the transplant team was satisfied that at the time consent was given:

- the donor was not a child;
- the donor was of sound mind; and
- consent was freely given.

The surgeon who will remove the organ or tissue is also required to obtain written consent from the prospective donor for the retrieval surgery to proceed. The surgeon has an independent ethical and legal obligation to ensure that the donor has given a valid consent and has been informed of the risks and alternatives.

## Additional considerations in documenting consent for children or dependent adults

Documentation of consent for children or dependent adults needs to describe clearly the steps that occurred, specifically that:

a) in addition to medical and social assessments (as required for all potential donors), psychological assessment by an appropriately experienced health professional was carried out to ensure that:

- the person's understanding was as thorough as possible consistent with his or her age, maturity and mental capacity; and
- there was no evidence of coercion; and
- ethical and legal assessments of the case were carried out and no impediments to donation were found; and

b) on the basis of the psychological, social, medical, legal and ethical assessments, the balance of benefits and burdens of donation was found to be in the person's best interests by an independent person or major hospital ethics committee (as per institutional protocol); and

c) written consent was given by the person's parent or legal decision maker.

## RECIPIENT DECISION-MAKING

It is the recipient's choice whether or not to accept a donation from a living directed or non-directed donor. If the potential recipient is unconscious, a child or a dependent adult, the family or other legally appointed decision-maker should be asked for consent to proceed.

Information should be provided to the recipient concerning the expected outcomes if transplantation goes ahead. The recipient (or the family if the recipient is unconscious) is entitled to information about the quality of the organ or tissue and any issues that may affect the recipient's health both in the short and the long term. However, in cases of non-directed donation, it is important that confidentiality is maintained so discussion should not include information that might lead to the recipient being able to identify the donor. The long-term harm of continued immunosuppression should also be discussed.

If consent for transplantation is given, this should be documented.

Any decision to not accept a living donation should not prejudice the recipient's place on the deceased organ or tissue waiting list.

## 3.3 ONGOING CARE OF DONORS

Donors should be offered medical and psychological care related to the donation process, for at least one year or until any complications have resolved. The health care professional who acted as an advocate for the donor through the donation process would be a valuable member of the team providing follow-up.

## RETRIEVAL

The donor's consent to undergo surgery is made on the understanding that it will be performed by an experienced and competent surgeon and that all possible steps will be taken to reduce the incidence of peri-operative complications.

Retrieval should be conducted in accordance with established guidelines (see Appendix B) and local protocols.

## MEDICAL AND PSYCHOLOGICAL FOLLOW-UP

Early follow-up of donors is essential to ensure that they have made a satisfactory recovery from the operation. Donors should then be monitored for both psychological and physical outcomes for at least 12 months postoperatively or until any complications have resolved, by the same team who assessed them pre-operatively. Particular attention should be given to noting donors' concerns about physical symptoms and their ongoing relationship with the recipient, helping donors debrief and reassess their coping strategies, and facilitating access to mental health care if required. The use of standardised instruments in these assessments (such as Short-Form 36) may assist with focussing discussion and ensuring a comprehensive assessment (Smith et al 2004).

Follow-up assessments may be conducted by the transplant centre and may be complemented by assessments carried out by the patient's GP (for example through an annual check-up).

### Possible adverse psychological outcomes

Although many donors recall the experience of donation positively, for some there is an emotional cost. Examination of psychological outcomes affecting donors suggests that:

a) risk factors for adverse outcomes include being a related donor but not a first-degree relative, ambivalence prior to the donation, donating to compensate for or repair past wrongs, or to restore their position in the family; and

b) some factors that might have been expected to be risk factors do not appear to be so — these include whether recipients lost their grafts or died, the occurrence of donor peri-operative medical complications, whether donors had pre-donation histories of psychiatric disorder, or the nature of the donors' past relationship with the recipient.

## WHEN DONATION WILL NOT PROCEED

When a donor is deemed unsuitable on medical grounds, arrangements should be made for appropriate medical care or referral. Likewise, should the donation be considered unsuitable due to psychological reasons, arrangements should be made for appropriate treatment or referral. In either case, considerable care needs to be taken in communicating why the individual is not considered suitable and explaining any implications for their health.

Prospective donors who decide not to proceed with donation or who are considered unsuitable on medical or psychological grounds should be offered counselling by a social worker, psychiatrist, psychologist or psychiatric nurse from the transplant team, with the aim of:

a) enabling the prospective donor to work through any feelings or conflicts that he or she may have around the decision not to be a donor;

b) for potential directed donation, helping the prospective donor to decide how he or she wants the intended recipient to be informed of the decision not to donate. Staff should be available to assist the potential donor to make a plan and carry it out; and

c) helping the prospective donor deal with the discovery of a serious health problem, where this applies.

The potential recipient may also need counselling if the potential donor withdraws.

## POOR OUTCOME OF TRANSPLANTATION

If the donated organ or tissue fails or is rejected, the donor should be informed in a supportive way, with attention paid to a suitable place, time and manner of giving the information. Recipients of directed donations should be given the opportunity to be involved in discussions as to how and when the donor should be informed. If these recipients wish to inform the donor themselves, support by a member of the transplant team should be offered. If non-directed donors have expressed the wish to be informed of outcomes of transplantation, they too should be informed in a sensitive manner. A member of the transplant team should be available to provide counselling as needed, including highlighting that the significance of the donation is not altered by a poor outcome and that the donor is not responsible for the result of the transplant.

Many donors maintain their positive outlook in the event of transplant rejection or failure. However, if emotional responses such as regret, guilt and diminished closeness to the recipient occur, continuing support should be provided to the donor by a relevant health care professional. Similar support should be provided to recipients who suffer guilt or regret if the transplant is not successful.

In the event that the recipient or donor should die, bereavement counselling should be offered to the surviving patient and involved family members. This can be provided by a member of the health care team such as a social worker, psychiatric nurse or psychiatrist, or referral may be made to an appropriate service in the community.

# FRAMEWORK FOR LIVING DONATION FOR ADULTS* (DIRECTED AND NON-DIRECTED DONATION)

**Prospective donor considers living donation**

**Prospective donor provided with information on the purpose and process of evaluation (see page 22)**

If consent to evaluation given

**Assessments**

| **Medical assessment** (see page 36) | **Psychological assessment** (see page 34) | **Social assessment** (see page 35) |
|---|---|---|
| • No biological incompatibility<br>• No medical/ surgical contraindications<br>• Minimal potential for infection of recipient | • Prospective donor accepts voluntary nature of donation<br>• No suggestion of coercion (overt or covert) or ambivalence<br>• No risk factors for adverse psychological outcomes | • Work-related issues<br>• Living arrangements<br>• Financial issues |

| | | |
|---|---|---|
| If no likelihood of significant physical harm from donation | If no likelihood of significant psychological harm from donation | If no likelihood of significant social harm from donation |

**Donor advocate appraisal of donation (see page 37)**

If no barriers to donation

**Surgical team decision on donation**

If no unreasonable risk to donor

**Competent donor gives consent to donation (see page 38)**

If consent is not given, donation does not proceed and reasons for withdrawal remain confidential

**Donation proceeds**

**Ongoing care of donor (see page 40)**

- Medical review
- Psychological review
- Availability of counselling and support

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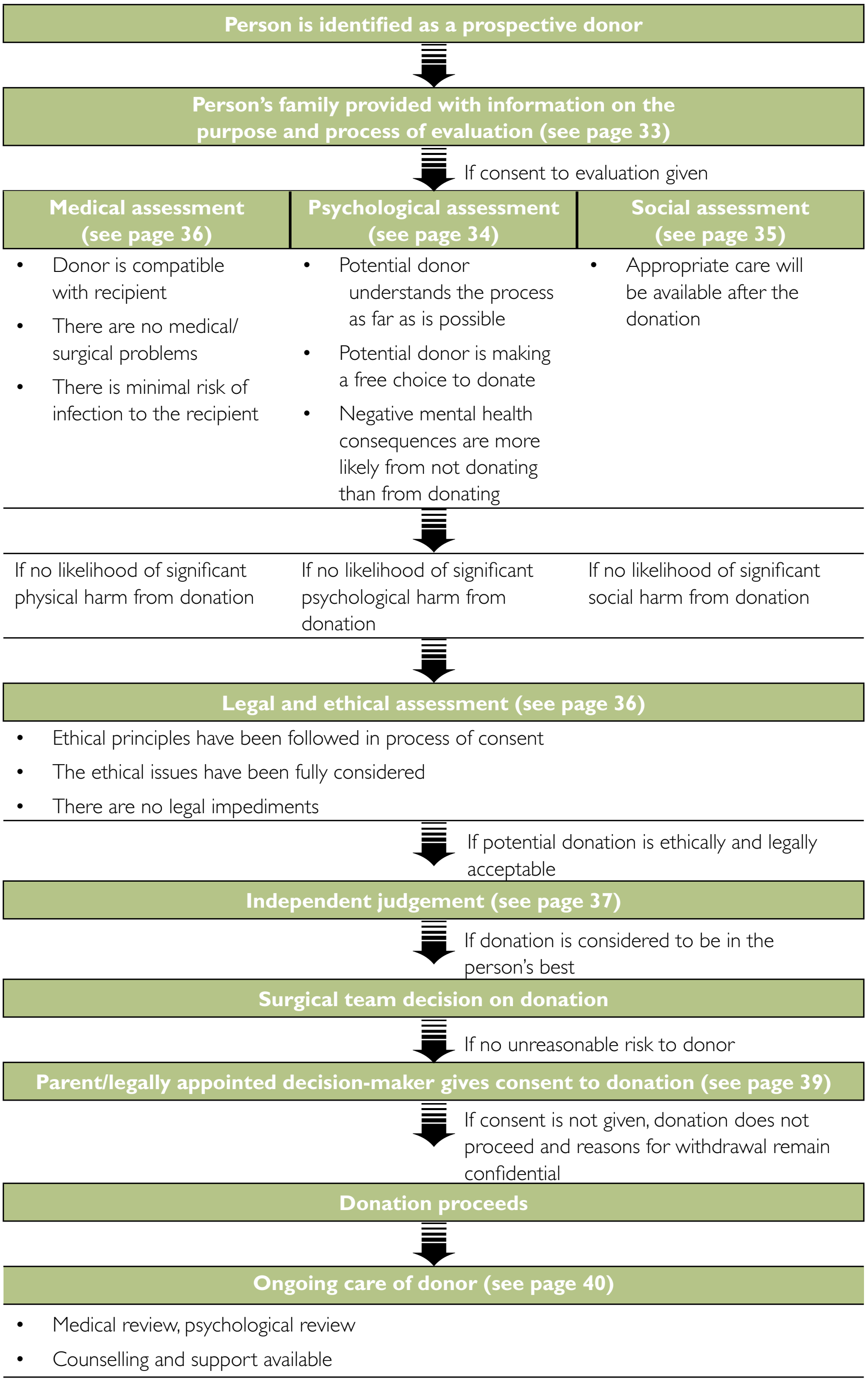
* This framework is meant as a guide only. The actual sequence of events will depend on individual circumstances and local practice.

# FRAMEWORK FOR LIVING DONATION FOR CHILDREN OR DEPENDENT ADULTS*



**Person is identified as a prospective donor**

↓

**Person's family provided with information on the purpose and process of evaluation (see page 33)**

↓ If consent to evaluation given

| Medical assessment (see page 36) | Psychological assessment (see page 34) | Social assessment (see page 35) |
|---|---|---|
| • Donor is compatible with recipient<br>• There are no medical/surgical problems<br>• There is minimal risk of infection to the recipient | • Potential donor understands the process as far as is possible<br>• Potential donor is making a free choice to donate<br>• Negative mental health consequences are more likely from not donating than from donating | • Appropriate care will be available after the donation |

↓

| | | |
|---|---|---|
| If no likelihood of significant physical harm from donation | If no likelihood of significant psychological harm from donation | If no likelihood of significant social harm from donation |

↓

**Legal and ethical assessment (see page 36)**

- Ethical principles have been followed in process of consent
- The ethical issues have been fully considered
- There are no legal impediments

↓ If potential donation is ethically and legally acceptable

**Independent judgement (see page 37)**

↓ If donation is considered to be in the person's best

**Surgical team decision on donation**

↓ If no unreasonable risk to donor

**Parent/legally appointed decision-maker gives consent to donation (see page 39)**

↓ If consent is not given, donation does not proceed and reasons for withdrawal remain confidential

**Donation proceeds**

↓

**Ongoing care of donor (see page 40)**

- Medical review, psychological review
- Counselling and support available

---

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

# 4 IMPLICATIONS FOR INSTITUTIONAL PRACTICE

This chapter outlines implications for institutions resulting from the ethical considerations given in Chapter 2. In order for living organ and tissue donation to be carried out ethically, processes should be coordinated, transparent and efficient.

Organisations can support ethical practice in living organ and tissue donation through processes that:

a) ensure sufficient time and attention is given to assessing potential donors;

b) promote ethical and sensitive treatment of donors, recipients and families;

c) support informed decision-making so that donors can reach a voluntary, independent decision about whether or not to donate;

d) ensure effective liaison among all health professionals;

e) recognise the importance of the benefit, safety and health of the recipient; and

f) maintain adequate records to facilitate oversight and review.

## Checklist for institutional ethical practice

**Roles and responsibilities**

- Ensure that health professionals involved in assessing donors have suitable experience and qualifications
- Ensure that health professionals involved in assessing the donor are, as far as possible, independent of the care of the transplant recipient
- Establish protocols for independent donor advocacy for competent adult donors
- Establish protocols for independent judgement in the case of children and dependent adults, including designating specific expertise or positions for inclusion in this process
- Establish and maintain systems for follow-up of donors, including recording outcomes, with due regard for confidentiality and privacy

**Institutional practice**

- Have a designated person whose role it is to ensure that local protocols on living donation are followed
- Ensure that local policies and protocols for ethical practice in living organ and tissue donation are included in peer review and internal medical audit activities as part of routine quality review processes
- Participate in institutional, State/Territory and national registers of living donation
- Ensure hospital resources allow for adequate staffing, ongoing professional development and strong governance in the short and long term.

## 4.1 ROLES AND RESPONSIBILITIES

Organisations are responsible for ensuring that the ethical principles concerning living organ and tissue donation are being met. This includes:

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

b) implementing policies to support informed decision-making;

c) providing support for ongoing training;

d) supporting a team approach; and

e) monitoring short and long term outcomes.

### HEALTH PROFESSIONALS INVOLVED IN ORGAN AND TISSUE DONATION

A multidisciplinary team of health professionals support and educate donors and their families, before, during and after donation. Health professionals involved in the assessment of the suitability of the donor to donate should, as far as possible, not be involved with the care of the transplant recipient. Members of the team may include:

a) *Medical specialist* (eg physician, renal specialist) — assesses the medical and physical suitability of the donor and provides care before the operation, during hospitalisation and at follow-up. The donor and recipient each have their own specialist care before donation but may be cared for by the same team during and after surgery.

b) *Surgeon* — assesses whether there are surgical contraindications to the donation, is involved in the decision as to whether to proceed and performs the operation to remove the organ or tissue and the transplant surgery.

c) *Psychiatrist or psychologist* — assesses whether the donor is psychologically healthy and whether donation poses any particular risks.

d) *Social worker* — assesses whether donation poses financial or social risks to the donor and provides individual and family counselling.

e) *Living donor transplant coordinator* — coordinates the process and ensures that the donor is fully informed and has provided informed consent. The transplant coordinator is also the first point of contact for the donor before, during and after the donation operation.

f) *Nursing staff* — provide continuing care before, during and after donation.

g) *Physiotherapist* — assists with recovery and rehabilitation after surgery.

h) *Pain team* — ensures that the donor has adequate pain relief after the operation.

i) *Intensivist* — provides care to donors with complications.

### RESPONSIBILITIES

Specific responsibilities of the health professionals involved in organ and tissue donation vary by jurisdiction and institution. Availability of resources locally also influences roles and responsibilities. However the process is organised, it is essential that the following ethical criteria are observed:

a) the potential donor is provided with an independent advocate who is not involved in the care or decision-making of the recipient;

b) mental health professionals involved in the process have specific training;

c) the confidentiality of both donors and recipients is maintained where appropriate; and

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

## 4.2 INSTITUTIONAL PRACTICE

Hospitals that provide care to patients who may become donors and their families should ensure that there are local policies and protocols in place that are in accordance with the principles outlined in this document and national and State/Territory guidelines (see Appendix B). Hospitals should also ensure that there is a designated person whose role it is to ensure that these protocols are followed.

## GOVERNANCE AND OVERSIGHT

### Adult donors

Each institution where living donation of organs or tissues by adults may be considered should have protocols in place to ensure that:

a) potential donors undergo psychological, social and medical assessment by suitably qualified and experienced health professionals who are not directly involved in the care of the transplant recipient;

b) throughout the process of evaluation one of these health professionals has at least one confidential consultation with the potential donor; and

c) the donor has an independent advocate (who may or may not be involved in the assessments) who is involved in the final decision-making about donation.

### Children or other dependent donors

Each institution where living donation of organs or tissues by children or dependent adults may be considered should have protocols in place to ensure that:

a) assessment of donors who are under 18 years of age, or not competent to make decisions for themselves, is carried out by a team of professionals who are not involved in the care of the transplant recipient and who have medical, psychological, social, legal and ethics expertise; and

b) reports by these professionals are considered by a person or committee who can, in a timely manner, make the decision as to whether or not donation is in the best interests of the child or dependent person. This role could be filled by a clinical ethics committee or designated health professional who is not involved in care of transplant recipients.

## ADDITIONAL PROTOCOLS

Other areas to be covered by local protocols are likely to include:

a) responsibilities of different categories of staff;

b) referral to guidelines;

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

d) training for staff, in particular those who will be supporting decision-making by potential donors; and

e) record keeping and short and long term data collection for review of outcomes.

These aspects should be included in peer review and internal medical audit activities as part of the routine quality review processes of the institution and be subject to review by an appropriately constituted external body.

## SUPPORTING STAFF

Training, supervision and counselling and other suitable assistance should be available for staff. Hospitals should establish policies and protocols to ensure this occurs and is utilised. Inclusion of the operating room staff is particularly important. Organised debriefing sessions may also be helpful in providing an opportunity for formal peer support.

## ACCESS

To guarantee equitable access to living donation, institutions should ensure that living donation programs are provided in a culturally acceptable manner, with particular consideration of diverse cultural groups within the institution's catchment area.

## QUALITY IMPROVEMENT

Evaluation of donor and recipient experience and outcomes is an essential part of the process of living donation and transplantation. This is especially important for collecting information on outcomes for marginal donors. The minimum requirements include an annual review of early and late morbidity, graft function and mortality. Collection of information on donor and recipient satisfaction rates can also inform service planning.

**Consideration should be given to the establishment of a national register of organ donor and recipient outcomes, with results of activities published in the public domain. As well as raising community awareness of outcomes of living donation, such a register would allow comparison of institutional outcomes.**

# 5 EMERGING ISSUES IN LIVING DONATION

There are a number of emerging issues in living donation, which are discussed briefly below. The discussion does not attempt to cover all aspects of these issues as they require further investigation and debate. The aim is to highlight these matters for further community and professional discussion.

## DONOR EXCHANGE — PAIRED DONATION AND LIST EXCHANGE

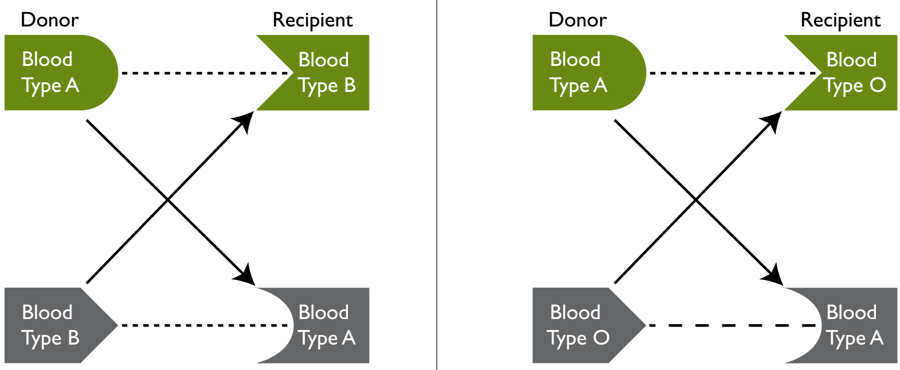
Processes for donor exchange have been developed to facilitate transplantation between living donors who are incompatible with their intended recipients. Through an exchange of organs, planned donations may proceed.

Implementation of donor exchange requires particular attention to ensure that the ethical principle of justice is met.

### Paired donation

With paired donation, potential donor-recipient pairs who are incompatible with each other can be matched with other incompatible donor-recipient pairs to exchange organs. Paired donation is currently practised in the Netherlands and United States, but it remains uncommon. Paired donation was introduced in Western Australia in late 2005, through legislative changes allowing donors from unrelated families to exchange organs and tissues. At the time of writing a limited number of paired donations have occurred in Western Australia. Paired donation remains illegal in other States and Territories.

**Figure 5.1** **Depictions of kidney paired donations**



**Conventional paired donation**

In a conventional paired donation, two donor/recipient pairs who are blood type incompatible exchange donors such that both resulting transplants are compatible. Conventional paired donations are limited to donors and recipients with blood types A and B.

**Unconventional paired donation**

In an unconventional paired donation, matching is expanded to include donor/recipient pairs who are incompatible because of a positive cross-match. As a result, donors and recipients with blood types O and AB also are eligible, provided that their incompatibility is a positive cross-match. Recipients exchange donors such that both resulting transplants are blood type and cross-match compatible.

Intended Pairs ■ ■ ■ ■
- - - - Blood Type Incompatible
— — Positive Crossmatch
—— Matched Pairing

Source: Montgomery et al (2005).

Donor-recipient pairs should be matched to avoid large age gaps. Both sets of operations should be performed simultaneously, to avoid a situation where the second donor refuses consent after his or her relative has received an organ from the first donor.

## List exchange

List exchange is a process in which a donor who is not compatible with his or her intended recipient offers to donate to a stranger on the list waiting for a deceased donor kidney and in return, the intended recipient advances on the waiting list. As with paired donation, this practice remains illegal in most States and Territories.

The movement of patients up the waiting list compromises established allocation protocols and has the potential to disadvantage other patients. However, list exchanges allow more patients to be transplanted than would be the case if list exchange did not occur because it introduces extra kidneys into the pool with the subsequent removal of patients from the deceased donor organ waiting list, and may allow others to avoid the list.

## SAVIOUR SIBLINGS

Saviour siblings is a term used to describe children who are conceived to provide matching cord blood or bone marrow for an existing sibling who is in need of transplantation and who has no suitable living donor within the family. Where local legislation permits, *in-vitro* fertilisation and pre-implantation genetic diagnosis is used to select embryos that will provide a good tissue match for their existing sibling for implantation. The genetic similarity between a child conceived in this way and an existing sibling means that the child will be a suitable cord blood or bone marrow donor for the older sibling. Embryos can also be tested and a child born to be a saviour child for a sick parent.

The ethical implications of this process are complex. These are discussed in Section 12.3 of the NHMRC *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (NHMRC 2004a; see Appendix B). However, the ethical principles associated with any living donation, and in particular those that apply to children (see Section 2.4), are relevant regardless of reproductive technologies that are employed to create the donor.

## DIRECTED UNRELATED LIVING DONATION

Overseas, the growing use of living donors has given rise to more controversial methods of organ and tissue solicitation, including private advertising, community-based groups soliciting on behalf of individuals and internet sites that link patients with potential living donors. Such arrangements are illegal in this country but can be accessed by Australians.

While these arrangements cannot be prevented, they should be discouraged because they bypass accepted ethical principles, especially justice, and medical processes of assessment and allocation, and make anonymity virtually impossible to maintain.

There is also concern that there is no mechanism for ensuring the accuracy of information submitted by potential donors and recipients. This may lead to important steps in assessment of risk and benefits being omitted. Independent assessment of potential donors contacted through direct solicitation is essential. Health professionals are also obliged to take reasonable steps to ensure that these donors undergo appropriate assessment and work-up (outlined in Chapter 3), and that no element of commerce is involved.

## FINANCIAL ISSUES

There are several financially-related ethical issues associated with living organ and tissue donation, ranging from reimbursement of expenses associated with being a living donor, to debate about payment of living donors, to overseas commercial transplantation programs which have implications for the Australian health system. These issues need further public discussion within the Australian context.

### *Reimbursement of living donors*

There may be financial barriers to becoming a living donor, including travel and accommodation costs, time off work and out-of-pocket expenses. Payments to reimburse living donors for certain expenses are made in a number of countries (eg New Zealand) but not in Australia. It may be ethically acceptable for people to be reimbursed for financial costs associated with being a living donor, but such reimbursement should aim to remove financial barriers to donation rather than act as an incentive to encourage people to donate organs or tissues. However, reimbursement for financial losses may be indistinguishable from direct payment for an organ, especially for those who are unemployed. Such payments may act as an inducement and may, in effect, constitute trade in human body parts which is illegal in Australia.

### *Trade in organs and tissues*

Trade in human body parts is ethically unacceptable and is also illegal in Australia. However, there is considerable debate in the United States and elsewhere regarding payment for organs and tissues. Some experts propose a regulated system of payment for living organ donors in order to increase the supply of organs for transplantation, while others remain vehemently opposed to this on the grounds that it erodes altruism and violates notions of equity and social justice.

In Australia, such payments might undermine the enormous social capital that exists in altruistic donations to blood bank and bone marrow services, the integrity of those services and the dependence on honesty in answering questions about risk factors. There is also a view that buying and selling human organs and tissues goes against a basic notion of respect for the dignity of the person and his or her body.

Both legal and illegal commercial transplantation programs exist in many parts of the world. Payment for donor organs now occurs in a number of countries, despite it being an illegal practice in most (Delmonico 2005a). In Iran, there is a government-sanctioned system of organ vending (Delmonico 2005a) and large commercial transplantation programs in China attract recipients from all over the world (Kennedy et al 2005). The option of buying an organ overseas is becoming increasingly available through the internet (Verran 2005), raising concerns about the exploitation of prisoners or those from poorer countries who have limited access to health care and no access to renal replacement therapy. The potential immorality of payment for organs is illustrated by the organ black markets that exist in a number of developing countries and lead to poor and vulnerable groups being exploited (Delmonico 2005a). Recognising that illegal organ trafficking is increasing, the 2004 WHO Resolution called for the international transplant community to protect people from 'transplant tourism' (World Health Assembly 2005).

There are significant implications for the Australian health system in providing ongoing care for overseas transplant recipients who are at risk of blood-borne diseases and other complications. While people should be strongly discouraged from obtaining an organ in this way, it is not ethical to withhold treatment from these patients, many of whom make the decision for a commercial transplant as an act of desperation. In addition, not funding immunosuppressive therapies for these patients would lead to the risk of graft failure and return to dialysis, with its attendant costs.

# 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 |

## CORRESPONDING MEMBER

| | |
|---|---|
| Dr Graeme Russ | Director, Nephrology and Transplant Services, Queen Elizabeth Hospital, Adelaide |

## 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 KEY INFORMATION SOURCES

## GUIDELINES

ABDMR (2005) *Operation Guidelines*. Australian Bone Marrow Donor Registry. www.abdmr.org.au.

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

Australian and New Zealand Society of Nephrology/Australian Kidney Foundation (currently being updated) *Transplantation: Living Kidney Donors*. www.cari.org.au/trans_living_updating.php.

NHMRC (2004a) *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*. Commonwealth of Australia.

NHMRC (2004b) *General Guidelines for Medical Practitioners on Providing Information to Patients*. Commonwealth of Australia. www.nhmrc.gov.au/publications

NHMRC (2004c) *Communicating with Patients. Advice for Medical Practitioners*. Commonwealth of Australia. www.nhmrc.gov.au/publications

NHMRC (2006) *Making Decisions about Tests and Treatments: Principles for better communication between healthcare consumers and healthcare professionals*. Commonwealth of Australia. www.nhmrc.gov.au/publications

NSW Health (2005) *Policy Directive: Living Kidney Donation (Including Directed and Non-Directed Donation).*

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

TSANZ (2003) *Guidelines for Non-directed Living Renal Donation in Australia*. Transplantation Society of Australia and New Zealand, Sydney. www.racp.edu.au/tsanz/oap7f.htm.

## 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*. Dept 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.

NHMRC (2006) *Cultural Competency in Health: A Guide for Policy, Partnerships and Participation*. Commonwealth of Australia.

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, San Francisco.

## LEGISLATION

*Therapeutic Goods Act* 1989

*Human Tissue Act 1983* (NSW)

*Human Tissue Act 1982* (Vic)

*Transplantation and Anatomy Act 1979–84* (QLD)

*Human Tissue and Transplant Act 1982* (WA)

*Transplantation and Anatomy Act 1983* (SA)

*Human Tissue Act 1985* (Tas)

*Human Tissue Transplant Act 1979* (NT)

*Transplantation and Anatomy Act 1978* (ACT)

## Online sources of legislation

| | |
|---|---|
| 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 |

## AGENCIES INVOLVED IN THE SECTOR IN AUSTRALIA

| Organisation | Website |
|---|---|
| Australasian Bone Marrow Transplant Recipient Registry | www.bmtnsw.com.au/abmtrr_about.php |
| Australasian Tissue Banking Forum | www.atbf.org.au |
| Australian and New Zealand Organ Donation Registry | www.anzdata.org.au |
| Australian Bone Marrow Donor Registry | www.abmdr.org.au |
| Australian College of Critical Care Nurses | www.acccn.com.au |
| Australians Donate | www.organdonation.org.au |
| Australasian Transplant Coordinators' Association | www.atca.org.au |
| Haematologists Society of Australia and New Zealand | www.hsanz.org.au |
| Kidney Health Australia | www.kidney.org.au |
| Transplant Nurses Association Inc | www.tna.asn.au |
| Transplantation Society of Australia and New Zealand | www.racp.edu.au/tsanz |

# C 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 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. An Organ Donation Working Party was established in early 2005. The committee 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).

## 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 submissions 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 (Australians Donate, Australian and New Zealand Intensive Care Society, Transplantation Society of Australia and New Zealand, Consumers' Health Forum, Australasian Transplant Coordinators' Association, AHMAC Organ Donation Working Group); seven State/Territory health departments; six other government organisations; seven State/Territory organ donation services; 40 other health and medical organisations; 21 transplantation units; four Aboriginal and Torres Strait Islander contacts.

The submissions were supportive of 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 organisations supporting donor families were asked to identify issues for inclusion in the four new documents.

### Public consultation 2006

In August 2006, the guidelines and the community booklet derived from the guidelines were advertised for public consultation. Submissions were received from 29 organisations and individuals.

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

a) further highlight the need for care to protect the interests of children and dependent adults and improve clarity around the process of consent for these donors;

b) strengthen discussion of the need for an independent advocate for adult donors;

c) improve accuracy and expand discussion of bone marrow donation;

d) make clearer the current situation in Australia in regard to paired donation, list exchange and compensation/re-imbursement for donors;

e) expand discussion on knowing and documenting the recipient's wishes;

f) clarify the role of the surgeon;

g) achieve consistency with the AHMAC Living Donor Transplantation Advisory group in regarding liver as a non-regenerative tissue; and

h) improve applicability of guidelines nationally (in context of varying legislation).

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

a) providing more information on the scope of the document;

b) expanding the section on issues for community discussion to include more information on the current situation in Australia;

c) including additional material concerning bone marrow donation;

d) re-organising and expanding material concerning donation by children and dependent adults to make a clearer distinction between the needs of these groups;

e) highlighting the importance of the roles of the independent advocate and the surgeon in the donation process;

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

g) simplifying language and improving grammar.

Additional revisions were also made to provide consistency between this document and the NHMRC guidelines for ethical practice for health professionals on deceased organ and tissue donation. These included:

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

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

c) improving layout.

## LITERATURE SEARCH

A literature search was conducted in October and November 2005. Relevant articles were drawn from international literature and examined, as were a variety of national and international organisations' views on organ donation.

## 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 professionals colleges and 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

| | |
|---|---|
| **Altruistic** | ‘Regard for others as a principle of action; unselfishness’ – eg a person who freely donates an organ or tissue without incentive or coercion. |
| **Dependent adult** | An adult who has impaired decision-making capacity, due to mental illness, psychiatric disability, intellectual disability, an acquired brain injury, or some form of dementia |
| **Directed donation** | Living donation of an organ or tissue to a relative or friend. |
| **Crossmatching** | A blood test to determine if a patient has antibodies against a donor’s antigens. Positive means the donor and patient are incompatible; negative means no reaction from the patient and the transplant may proceed. |
| **Leukapheresis** | A procedure in which white blood cells are separated from a sample of blood for transplantation. |
| **List exchange** | A matching service where a donor who is not compatible with his or her intended recipient donates to a stranger on the waiting list for a deceased donor kidney and in return, the intended recipient advances on the waiting list. |
| **Living donor** | A person who voluntarily gives organs and/or tissues for the purpose of transplantation into another person. |
| **Non-directed donation** | Living donation of a kidney to the general kidney pool, or donation of bone marrow through registration on a bone marrow donor registry, for transplantation into the most suitable recipients on the waiting list for deceased donor organs and tissues |
| **Organ** | A part of the body that performs vital function(s) to maintain life. These include the kidney, heart, lung, liver and pancreas. |
| **Paired donation** | Potential donor-recipient pairs who are incompatible with each other are matched with other incompatible donor-recipient pairs to ‘exchange’ organs. |

| | |
|---|---|
| **Recipient** | A person who receives organs and/or tissues from another person (the donor). |
| **Saviour sibling** | A child born following pre-implantation genetic diagnosis to act as a matched donor for an existing child who requires tissue transplantation. |
| **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. It is similar to blood grouping and cross-matching. |

# ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| ABMDR | Australian Bone Marrow Donor Registry |
| AHEC | Australian Health Ethics Committee |
| AHMAC | Australian Health Ministers' Advisory Council |
| AIHW | Australian Institute of Health and Welfare |
| ANZDATA | Australia and New Zealand Dialysis and Transplant Register |
| ANZICS | Australian and New Zealand Intensive Care Society |
| ANZOD | Australia and New Zealand Organ Donor Registry |
| AODR | Australian Organ Donor Register |
| ASERNIP/S | Australian Safety and Efficacy Register of New Interventional Procedures-Surgical |
| ATCA | Australasian Transplant Coordinators' Association |
| NHMRC | National Health and Medical Research Council |
| TSANZ | Transplantation Society of Australia and New Zealand |
| UNOS | United Network for Organ Sharing (US) |

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