

Kidney Donation - Living (including Directed and Non-Directed Donation)

Document Number PD2009_013

Publication date 26-Mar-2009

Functional Sub group Clinical/ Patient Services - Human Tissue
Clinical/ Patient Services - Medical Treatment
Clinical/ Patient Services - Surgical

Summary This Policy Directive applies to all public health organisations and sets out standards and conditions for donation of a single kidney by an adult living person for transplantation into another person. The most recent review of this policy removes an upper age limit on both directed and non-directed donors. The 2008 review specified the prohibition of directed deceased donation and conditional donation in NSW while clarifying the position on proceeding to transplant in the circumstance where an adult donor dies in the process of directed living kidney donation.

Replaces Doc. No. Kidney Donation - Living (including Directed and Non-Directed Donation) [PD2008_062]

Author Branch Health Research and Ethics

Branch contact Julie Letts 9391 9465

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Divisions of General Practice, Public Hospitals

Audience All clinical and medical staff involved in transplants

Distributed to Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

Review date 26-Mar-2014

File No. 03/9129-3

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

KIDNEY DONATION - LIVING (INCLUDING DIRECTED AND NON-DIRECTED DONATION)

Introduction

This Policy Directive states the Department's policy in relation to both living directed and non-directed kidney donation. In NSW, kidney transplantation procedures include use of both cadaveric organs sourced from deceased donors and kidneys donated by living people. 'Directed' donation where the donor agrees to donate their kidney for transplantation to an identified recipient, usually a spouse or partner, family member, or close friend has occurred in NSW for a number of years. 'Non-directed' donation is where the donor donates to any suitable 'stranger' on the waiting list.

This Policy Directive should be read in conjunction with the following NSW Department of Health policies:

PD2005_406 Consent to Medical Treatment - Patient Information, and;

PD2005_341 Human Tissue – Use/Retention of including Organ Donation, Post Mortem Examination and Coronial Matters

Chief Executive and persons in charge of renal units should bring the contents of this Policy Directive to the attention of those involved in the assessment and management of living kidney donors.

Professor Debora Picone AM
Director-General

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

LIVING KIDNEY DONATION (INCLUDING DIRECTED AND NON-DIRECTED DONATION)

1. Application of this Policy Directive

This Policy Directive applies to all public health organisations.

2. Scope of this Policy Directive

This Policy Directive applies to donations of a single kidney by an adult living person for transplantation into another person.

3. Types of living donors

There are three general categories of living kidney donors:

- the genetically related donor (generally parent, son, daughter, sibling, aunt, uncle, nephew, niece, cousin);
- the emotionally related donor (such as a spouse, friend or carer with whom they have a genuine close relationship);
- the non-directed donor, also known as the “good Samaritan” donor or the “altruistic stranger” donor. Such a donor wishes to donate a kidney to an unspecified but suitably matched person on the deceased donor waiting list.

4. General points

- 4.1 Donation of a single kidney by genetically or emotionally related donors is a well-established practice in NSW and is recognised as being ethically acceptable both here and overseas.
- 4.2 Non-directed kidney donations from living donors are also permissible, provided all the requirements of this Policy Directive are met.
- 4.3 All kidney donations should be undertaken in sites recognised as established centres for performing renal transplantation.
- 4.4 Donors may be admitted as public patients and the costs associated with their management will be covered under the normal arrangements. A donor may incur some expenses if they choose to be admitted as a private patient in a public hospital. Other expenses including costs of a general practitioner referral are to be met by the donor. Directed and non-directed donors may be considered for travel and accommodation support under applicable programs, for example the Isolated Patient Transport and Accommodation Assistance Scheme (IPTAAS).

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

- 4.5 Should directed and non-directed donors claim sickness benefits, this would not be in breach of the *NSW Human Tissue Act 1983*.
- 4.6 There is no 'right' to be a kidney donor. A public health organisation has a discretion not to accept a willing donor if it is considered not to be in the donors or the recipients best interests.
- 4.7 Living kidney donation is a process including (but not limited to) donor assessment, anaesthesia and surgery. If a donor dies at any point in the process of acceptable directed living donation, then directed donation may still be permitted. In this event, organs, other than the directed kidney, may be allocated via the deceased donor organ pool, provided the consent of the Senior Next-Of-Kin is given for their procurement in accordance with the NSW Human Tissue Act.

4.8 Prohibition on the Sale of Organs

- 4.8.1 Any agreements, which entail supply of an organ or tissue in exchange for the payment of valuable consideration to the donor are prohibited in NSW by the *Human Tissue Act 1983*.
- 4.8.2 The following arrangements are not permitted in NSW.
- The sale of organs and tissue.
 - Donation of a kidney in exchange for another person (for example, the donor's relative or friend) receiving priority on the waiting list for a cadaveric donation.
- 4.9 Staff of public health organisations should not participate in any arrangements that are known to be in contravention of the *Human Tissue Act 1983*.

5. Guiding Principles for living donation

- 5.1 In any living donation, the interests of the donor and the recipient are of equal importance.
- 5.2 The donor has an altruistic desire to assist the recipient generally.
- 5.3 Directed deceased donation, where an individual stipulates that at their death, any of their organs or tissue is exclusively intended for transplantation to a particular recipient, is not permissible.
- 5.4 'Conditional' donation, that is where a donor nominates, or excludes certain class/es of recipient, for example based on conditions of age, sex, religious belief or sexual orientation is not permissible. This applies to living and deceased donation.

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

- 5.5 The donor must have capacity for informed consent and be of sound mind.
- 5.6 Donor consent is voluntary and non-coerced. The potential donor is under no obligation to proceed with donation once donor assessment has begun.
- 5.7 The competent donor provides consent. Substitute consent to living kidney donation is not permissible.
- 5.8 The donor is 18 years of age or older. Children are explicitly excluded as donors of kidney tissue under the requirements of this policy.
- 5.9 There is a 24-hour 'cooling off' period for directed donations in which donations must not proceed following donor consent. For non-directed donations, a period of 3 months is required in the assessment process related to timeframes for sequential psychological assessment (see 8.5.1).
- 5.10 The donor may withdraw at any time before surgery i.e. the time of administration of sedative) without the need to give a reason.
- 5.11 It is reasonably expected that the donor will not suffer significant psychological and/or emotional harm by the donation process.
- 5.12 The donor principally determines the acceptability of the potential risks or harms to him or herself, providing there is understanding of risks and no contraindications. However, the donor surgeon has a duty of care to the donor and must also agree with a decision to proceed with donation.

6. Legal Framework

- 6.1 *The Human Tissue Act 1983* covers donation of regenerative and non-regenerative tissue by adults and minors.
- 6.2 The Act allows living adults to donate non-regenerative tissue (including kidneys) if certain requirements are met. The donation of non-regenerative tissue for the purposes of transplantation (including kidneys) by a child, as defined in the Human Tissue Act, is prohibited.
- 6.3 Certification by a Medical Practitioner

The statutory requirements for donation of kidneys by living adults are as follows:

- 6.3.1 The donor must give written consent.

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

6.3.2 Pursuant to the *Human Tissue Act 1983*, a medical practitioner, other than the medical practitioner who will perform the surgery to remove the tissue, must certify that:

- the donor's written consent was given in his or her presence;
- the donor had explained to him or her, before the consent was given, the nature and effect of the removal of the organ from the donor's body;
- at the time the consent was given the medical practitioner must be satisfied that:
 - the donor was not a child;
 - the donor was of competent mind; and
 - the consent was freely given.

6.3.3 The kidney in directed donation must not be removed until 24 hours has passed from the time the consent was given.

6.4 Consent to Surgery for the Removal of the Kidney

6.4.1 The above certification is not the written consent for the donor nephrectomy. The surgeon who will remove the tissue must obtain written consent for the surgery to remove the kidney, in accordance with the Department's consent policy and the additional requirements set out in sections 6.3 and section and 7.1 of this policy directive.

6.4.2 The surgeon who removes the kidney has an independent legal obligation to ensure that the donor has given a valid consent and has been informed of risks and alternatives (see section 7 below), regardless of whether the medical practitioner who referred the donor to the surgeon also discussed these issues with the donor. The surgeon who removes the kidney cannot rely on the consent and information provided to the donor by the other medical practitioner in order to discharge his or her own duty of care. Certification under the *Human Tissue Act 1983* by a medical practitioner who does not perform the surgery does not impact in any way upon the duty of the surgeon to inform the patient of material risks and alternatives.

6.4.3 The removal of the kidney is prohibited if the donor revokes their consent. The donor may revoke their consent at any time prior to the preoperative sedative for removal of the kidney.

7. Requirements for ALL living kidney donations (directed and non-directed)

In relation to all living kidney donations, local protocols must be developed which cover the following matters.

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

7.1 Information for donors

7.1.1 Written material should be made available to recipients and families about kidney transplantation, including the possibility of living donor transplantation. It must then be up to an interested potential donor to indicate their willingness to begin an assessment process. Such information should include:

- Reason for using a live donor as opposed to deceased donation;
- A full description of the procedure;
- Implications of the procedure for the donor, such as preparation for surgery by drugs or diet, hospital admission;
- Risks to the donor inherent in the procedure including:
 - Surgical risks;
 - Immediate complications as a result of the procedure including risk of kidney failure;
 - Risk of death;
 - Long term risks.
- The process of recovery for the donor, including:
 - Physical rehabilitation and length of expected recovery time;
 - Level of probable pain or discomfort after procedure;
 - Inhibition of normal activity;
 - Time off work required (and related financial impact such as access to life insurance etc.).
- The likely outcomes for the recipient (including possibility of failure of the donation, possible complications, prospects of success);
- Possible changes to the donor/recipient relationship (including possible feelings of 'ownership' towards the recipient by the donor, the donor feeling the need or right to make demands upon the recipient, and that the donor may be the object of feelings of gratitude by the recipient);
- That the donor may choose not to proceed with donation at any time before surgery and that it is not a foregone conclusion that donation will occur once donor assessment has begun.

7.1.2 Attention should be paid to ensuring adequate understanding in the donor and recipient, consistent with informed consent standards, and may require interpreter assistance in some cases.

- Standard information for living kidney donors is available at http://www.health.nsw.gov.au/pubs/2004/kidney_donation.html

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

7.2 Assessment of donor's psychosocial (mental) health

7.2.1 Assessment of directed and non-directed donors' psychological health and psycho-social circumstances shall be undertaken during the assessment process (see 8.5 for non-directed donors). Adequate assessment of the following should be undertaken during the donor evaluation process. This may, in some circumstances, require assessment by a suitably qualified mental health professional. The decision to proceed with donation should take account of the following aspects of the donor's psychological health and psychosocial circumstances:

- Competence of the donor to consent;
- Understanding of the risks and benefits of the procedure;
- Motivations of the donor;
- Relationship with the recipient and associated family (directed donation) and attitude to donation by those close to a potential non-directed donor;
- Any undue pressure, or any coercion, threats or inducements potentially affecting the donor's decision;
- Any mental illness, personality disorder or substance abuse potentially affecting the donor's decision to donate or potential postoperative outcome;
- The donor's understanding and acceptance of the requirement for anonymity (non-directed donation);
- The donor's understanding of the principle that no financial or other benefits are to be sought from the recipient, the public health organisation or any other person as a result of the donation; and
- Support mechanisms for the donor during and after the procedure.

7.2.2 All potential donors must be able to decline donation for any or no reason. In particular, directed donors must be able to decline without disclosure of the reason for donation not proceeding to the recipient, their family or others close to the recipient.

7.2.3 A potential directed donor may be deemed 'unsuitable' for donation according to reasons applicable in one or more of the following broad categories:

- Medical or surgical reasons;
- Infection;
- Biological incompatibility, for example tissue matching; or
- Psychosocial reasons, including situations in which the prospective donor decides to decline surgery.

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

7.3 Assessment of donor's medical suitability

The donor's medical suitability for donation is to be assessed by a renal physician independent of the recipient's transplant team, in accordance with relevant selection criteria issued by the NSW Transplant Advisory Committee (TAC), and in accordance with good medical practice.

7.4 Information for recipients

The recipient must be provided with information regarding the following matters, in addition to all information routinely provided prior to kidney transplantation relevant to the surgical procedure, prior to giving consent for receipt of a donation from a living person:

- Feelings the recipient may encounter if the donation fails;
- Possible changes in donor-recipient relationships (for directed donations);
- Possible feelings of ownership towards the recipient by the donor and the possibility of demands made by the donor;
- Possible debt of gratitude or feelings of obligation felt by the recipient towards the donor;
- Possible psychological consequences if donation has harmful effect on donor;
- The right of the donor to withdraw at any time, without the provision of a reason for doing so, and the possible cancellation of the procedure.

7.5 Recipient's consent

7.5.1 It is the recipient's voluntary and non-coerced choice whether or not to accept a donation from a living directed or non-directed donor. Any decision not to accept such a donation shall not prejudice the recipient's place on the cadaveric waiting list.

- The potential recipient is under no obligation to proceed with donation once donor assessment has begun.

7.5.2 A recipient's consent to the procedure must be obtained in writing in accordance with the Department's policy on consent.

8. Additional requirements for non-directed kidney donations ONLY

All the requirements set out above must be met, and in addition, the following matters are to be addressed.

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

8.1 Oversight of the process by the Transplant Advisory Committee

All non-directed kidney donations are to be oversighted by the Transplant Advisory Committee that operates under the auspices of NSW Health. The purpose of such oversight is to:

- Monitor the operation of the new policy;
- Allow for assessment of the new policy;
- Ensure transparency in the assessment and allocation procedure;
- Facilitate negotiations about location of donor and recipient surgery (see 8.7)
- Allow for the making of recommendations in relation to the review of the policy.

8.2 Institutional Discretion

8.2.1 It is in the discretion of each individual public health organisation to determine whether or not it will assist in assessing potential non-directed donors or undertake donor nephrectomy in the non-directed donation setting.

8.2.2 It is at the discretion of each transplant unit to determine whether or not it will receive kidneys from non-directed donors.

8.2.3 If a physician, surgeon or unit does not support non-directed kidney donation then that donor should be referred to a unit that does support the practice.

8.3 Anonymity

8.3.1 All reasonable steps are to be taken by the Transplant Advisory Committee, the transplant team and relevant medical and clinical staff to preserve the donor's and the recipient's anonymity through the donation and transplantation process.

8.3.2 Health professional's involvement in any desired contact between the non-directed donor and recipient may only proceed according to established TAC protocol, as based on the provisions in the *Human Tissue Act 2003*, that recognises the potential desire of recipients or donors for continued anonymity.

8.4 Donors must approach/be referred to the public health organisation

8.4.1 To be accepted as a non-directed donor, the donor must have raised the issue of donation with their primary health care provider or public health

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

organisation of their own accord, and not in response to any invitation by the public health organisation, a recipient, or a recipient organisation.

- 8.4.2 All potential donors should obtain a referral from their general practitioner to a relevant renal physician at a public health organisation. Persons who contact a public health organisation about wishing to be a donor should be provided with preliminary information and advised to seek advice and referral from their general practitioner. The same renal physician should not manage the donor and recipient.
- 8.4.3 Public health organisations shall not advertise for, or otherwise encourage individuals, to become non-directed donors.
- 8.4.4 Public health organisations shall not encourage potential recipients, recipient organisations, or other health care providers to advertise for non-directed donors.

8.5 Assessment of the non-directed donor's mental health

- 8.5.1 The potential donor should be assessed by a suitably qualified mental health professional (such as liaison psychiatrist with advice from a psychologist as appropriate) on at least two occasions, with at least three months interval between the first assessment and the second assessment, to allow the potential donor time to consider all information provided to him or her regarding the donation (see also 7.1.2).
- 8.5.2 Acceptance to be a non-directed kidney donor is contingent on that person being willing to undergo such psychological assessment.
- 8.5.3 A suitably qualified mental health professional should provide a written opinion concerning aspects of the donor's psychosocial circumstances, in conjunction with the requirements of 7.2.1, ascertaining whether or not the following pre-conditions for non-directed donation are met:
- The potential donor is competent to make such a decision;
 - The motivation/s of the donor are substantially altruistic; and
 - No significant psychological harms are likely to be associated with the non-directed kidney donation.
- 8.5.4 A person shall not be accepted as a non-directed donor if the above opinion indicates that it is not in their best interests.

8.6 Final decision is discretionary

- 8.6.1 While the donor principally determines the acceptability of any potential risks or harms to him or herself, providing there is understanding of the risks and no contraindication, the donor surgeon also has a duty of care

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

to the non-directed donor and must also agree with their decision to proceed with donation.

8.6.2 There is no right to be a kidney donor. A public health organisation has a discretion not to accept a willing donor if it is considered not to be in the donor's or recipient's best interests.

8.6.3 The non-directed donor may not demand or place limitations on a recipient's eligibility to receive their donated kidney, for example based on age, religious, racial, cultural, or criminal status (5.4).

8.7 Recipient selection/allocation

8.7.1 Allocation of a non-directed kidney will be to the most appropriate consenting recipient in NSW according to the National Organ Matching Scheme allocation formula for the deceased donor waiting list.

8.7.2 The Transplant Advisory Committee (or sub-committee) must approve of the recipient selection in writing. The Committee may approve selection of a lower ranking recipient, if appropriate in the circumstances.

8.7.3 Living donation should proceed such that ischaemic time affecting the donated kidney is minimised. Potential donors, or on occasion recipients, may need to travel to a centre for surgery other than where they were assessed. Donor and recipient teams should negotiate the most appropriate location of donor and recipient surgeries through TAC.

8.8 Recipient choice

8.8.1 It is advisable at the initial point of assessment for transplantation that the transplant recipient is asked by the treating unit whether they would potentially accept a donation from a non-directed donor. If the patient would be prepared to do so, they should be informed about whether that unit could accommodate such an option.

8.8.2 At the time of allocation of a non-directed donated kidney, the potential recipient should be informed that transplantation of such a kidney is proposed in their particular case.

8.9 Assessment by the Transplant Assessment Committee

After the relevant assessments have taken place, all reports and relevant medical information about the donor and the intended recipient are to be forwarded to the Transplant Advisory Committee (TAC) or its sub-committee for assessment. Information about the donor is to be submitted on a de-identified basis. Information about the recipient will be identified and the recipient's consent to forwarding of this information should be obtained.

Title: Living Kidney Donation (Including Directed and Non-Directed Donation)

The TAC will notify the public health organisation whether or not the non-directed donation may proceed.

8.10 Ongoing Monitoring

Both directed and non-directed donors should be informed of the need for ongoing future contact with the health care institution for the purposes of:

- Ongoing monitoring of individual donors' clinical outcomes, including psychological outcomes after donation.
- Health assessment and potential participation in research in relation to non-directed donation and transplantation. All future health assessments of donors and participation in research must be voluntary with consent obtained at the relevant time.

8.11 Follow-up

Public health organisations shall keep appropriate records regarding non-directed donors and recipients to allow for ethically approved research into future outcomes to be facilitated.