

## LIVING NON-DIRECTED KIDNEY DONATION

### DISCUSSION DOCUMENT

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Attachment 1: Draft policy on living, non-directed donation	

## **1. Purpose of this document**

In NSW, kidney transplantation procedures include use of both cadaveric organs sourced from deceased donors and kidneys donated by living people. Living donation currently is only permitted where it is 'directed', that is the donor agrees to donate their kidney for transplantation to an identified recipient, usually a spouse or partner, family member, or close friend. This practice 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. Non-directed donation is not unlawful under the Human Tissue Act, but has not been practiced in NSW owing to unaddressed ethical and other concerns with the practice.

NSW Health has produced a draft policy on non-directed kidney donation, in liaison with the NSW Transplant Advisory Committee (Attachment 1). The purpose of this consultation document is to seek community and health professionals' views on this policy and on several aspects of donation by living individuals. These include:

- Whether the draft policy sets out adequate procedures surrounding directed kidney donations;
- Whether non-directed kidney donation should be permitted; and
- If so, whether the draft policy sets out adequate procedures for non-directed donations, in particular:
  - Are the provisions surrounding the assessment of donors adequate (paragraph 7.4 of the *Draft policy*)
  - Is it appropriate to prevent conditional donations (paragraph 7.5.2 of the *Draft policy*)

## **2. Background to policy development**

Nearly three years ago, the then Chief Health Officer requested the NSW Transplant Advisory Committee (TAC) formulate a policy regarding non-directed kidney donation. The TAC consists of representatives of all clinical specialities in transplant medicine in NSW, as well as some non-transplant specialities (eg. intensive care specialists, emergency physicians). A consumer representative has been invited to join the Committee.

The Chief Health Officer's referral followed repeated requests by some individuals in the community to become non-directed kidney donors, which were raised with public health organisations, the Department, the Minister, in Parliament and in the media. At present, it is estimated that there are 5 to 20 individuals statewide wishing to become non-directed donors. Previously, several non-directed donors from Australia have travelled overseas to donate a kidney to those countries' waiting lists (personal communication).

It was agreed between the Department and the TAC that it was appropriate for any such policy to be issued under the authority of the Department of Health. The Department (Health Ethics Branch) and the TAC consulted together to produce the attached draft policy.

The NSW Health Clinical Ethics Advisory Panel (the Panel) considered the issue of living, non-directed kidney donation (and related draft policy) at a meeting in December 2003 at which they:

- Recommended wider consultation on the draft policy, in particular in relation to psychological assessment of the donor;
- Raised issues on the scope of directed donation in NSW; and
- Raised issues about whether, if living non-directed donation is permitted, donors should be able to place certain conditions on their donation.

### **3. Application of policy**

The draft policy aims to formalise requirements for the existing practice of directed donations in the NSW public health system, and set out parameters for the new practice of non-directed donations, if such a practice is found to be acceptable to the community.

The law only allows kidney donation by adult living persons. **Living persons under 18 years of age may not, in any circumstances, provide a kidney for transplantation (either directed or non-directed). The attached draft policy applies only to adult donors.**

### **4. Scope of policy**

The draft policy is confined to issues relating to kidney donation by living persons. There are several other organs that can be removed from living donors and used for transplantation, including parts of the liver, lungs and bowel. However, it is determined that this draft policy be limited to kidney donation from living persons at this stage with other organ donations by living persons being considered at a later stage.

**The draft policy and this paper do not deal with cadaveric kidney donation practice.**

### **5. Single living kidney donation**

The first successful renal transplant was performed in 1954 from a donor who was the recipient's identical twin.<sup>1</sup> Living donation by related donors has become widely practised in Australia and overseas since that time.

Table 1. shows the number of individuals awaiting kidney transplant, and recent cadaveric and living kidney donations.<sup>2</sup> NSW has one of the lowest cadaveric organ donation rates in the world. Even if substantial measures were taken to improve this situation, it is unrealistic to expect that even a significant increase in cadaveric donation rates would remove the perceived need for living donation. However, it is also not anticipated that non-directed donations could ever meet the short fall in organ supply.

Living donor transplants now yield better results than cadaveric transplants.<sup>3</sup> Numerous clinical studies have shown that the rates of patient and graft

survival are similar for transplants from living unrelated donors as for living related donors.<sup>3</sup> Approximately 40-50% of all current kidney donations in Australia are from living donors while in some centres this is as high as 60% (personal communication).

## **6. Kidney donation by living persons in other jurisdictions**

The World Health Organisation in 1991 developed a set of *Guiding Principles on Human Organ Donation*<sup>4</sup> that have considerably influenced professional codes, national and state legislation, and the policies of intergovernmental organisations. These *Guiding Principles* emphasise a preference for cadaveric over living donors as a source of organs and tissue (except for regenerative tissues). The WHO now recognises that organ supply problems worldwide have meant that the practice of living organ donation has continued to grow. The May 2003 WHO report<sup>5</sup> states that globally in 2002, nearly half of all transplanted kidneys came from living donors, and up to 80% in low-medium income countries. WHO is now considering updating the *Guiding Principles on Human Organ Donation* to support living organ donation, in part also related to a recognition that improvements in immunosuppression have reduced the need for living donors to be genetically related to the recipient. The May 2003 WHO report states that the updated WHO guidelines will emphasise even more strongly the need for, and challenges with, informed and voluntary consent in living donors, and the need for appropriate safety and outcome monitoring in this donor population.

The laws of other jurisdictions in respect of living kidney donation differ, and are discussed below.

### Other Australian States and Territories

Transplant law is basically uniform throughout the Australian States and Territories, and does not prohibit either directed or non-directed kidney donation.<sup>6</sup> However, with the exception of one centre in SA, non-directed donors have not been accepted in other Australian jurisdictions to date. The Queen Elizabeth Hospital in SA has policy, based on national guidelines, permitting non-directed kidney donation. One donation has occurred to date and another donor has been assessed as suitable (personal communication).

### New Zealand

Clinicians involved in the development of this policy note that there have been non-directed kidney donations in Christchurch, New Zealand. Some of these are from Australian donors who are presently unable to donate in this country. However, the precise law governing donations was unable to be located.

### United States of America

In the USA, the Anatomical Gift Act does not prevent directed or non-directed donations. The Ethics Committee of the *Organ Procurement and*

*Transplantation Network/United Network for Organ Sharing* (the US organ allocation body) has endorsed non-directed living donation as morally commendable and ethically acceptable.<sup>7</sup> A consensus statement authored by an executive group representing US transplant physicians and surgeons and the National Kidney Foundation, states that non-directed donation is ethically acceptable if the same criteria are met as applies to directed donations.<sup>8</sup> Non-directed donations are not uncommon in the US.<sup>3</sup> However, the literature shows that some US centres will not accept non-directed donations.<sup>1, 9-10</sup>

It appears that the practice of “paired donations” and donations in return for providing favourable treatment may be utilised in the United States.<sup>1</sup> Such practices include the following:

- A donor may wish to donate to his or her relative but is incompatible. Instead, the donor agrees to make a non-directed donation anonymously to a person on the cadaveric waiting list, in return for his or her relative being given priority for the next available suitable cadaveric donation.
- A donor may wish to donate to his or her relative but is clinically incompatible. The transplant unit finds another potential donor who is in the same position. Neither donor is compatible with their chosen recipients, but may be compatible with each other’s chosen recipients. Accordingly, the donors do a “swap” of intended recipients to facilitate donation in each of them.

In NSW, the Department is of the view that both these practices contravene section 32 of the Human Tissue Act 1984, which prohibits the giving or receiving of any valuable consideration in return for organ donation. Such practices are therefore ruled out by the draft policy.

### United Kingdom

UK legislation prohibits living organ donation except to a genetically related person, unless the donation is approved by the Unrelated Live Transplant Regulatory Authority (ULTRA). A genetically related person includes parent, child, siblings, uncles, aunts, cousins, nieces and nephews (of either the whole or half blood). Notably, spouses are not included, and therefore spousal donation requires ULTRA approval.<sup>11</sup>

ULTRA requires that there is an established relationship between the donor and recipient (spouse, partner, close friend) and that relationship has to be proven to ULTRA’s satisfaction. Accordingly, non-directed donations cannot lawfully take place in the UK.

### Canada

Each Canadian state is responsible for legislation governing human tissue transplants. The legislation is generally uniform throughout the states, and

allows a living adult to consent to the donation of tissue to any other living person.<sup>12</sup> Accordingly, directed and non-directed transplants would not be unlawful.

## Europe

A few European jurisdictions limit permissible recipients of living organ donation. It appears that the Russian Federation and Portugal prohibit donations other than to relatives.<sup>13</sup> Spain prohibits donations other than to a “specified person”, thus effectively prohibiting non-directed donations.<sup>13</sup> More common in European legislation is a clinical criteria for donation. Some countries prevent donation if it presents a serious risk to the donor’s life or health (Turkey, Romania, Spain, Finland, Denmark).<sup>13</sup> Some add to this a requirement that a cadaveric donation is not available (Belgium).<sup>13</sup>

In Germany, a transplant surgeon made a non-directed kidney donation to reassure potential donors of the safety of donor nephrectomy. Shortly thereafter, new legislation made anonymous non-directed donation illegal.<sup>1</sup> Living donation is permitted only if the donor has a special relationship to the recipient, that is they are a direct relative, spouse, long term partner.

## Asia

Taiwan has the tightest restrictions on living donations, allowing donation only by relatives up to the third degree of consanguinity. Neither Japan nor Korea has any legal restrictions on classes of recipients from living donations. Hong Kong allows donation from friends, provided the bond of friendship can be proven and supported.<sup>14</sup>

## **7. Risks of living kidney donation**

Kidney donation is considered to be a relatively safe procedure for the donor. Risk of death for the donor is generally quoted in the literature as being 0.03%.<sup>1, 3</sup> As noted in one US study, this makes its mortality risk approximately the same as driving a car in the US for two years or giving birth to two children.<sup>1</sup> US literature indicates that there have been at least two directed kidney donor deaths and one case of a directed donor who existed in a persistent vegetative state for 18 months.<sup>15</sup> Details of the cause of these outcomes were not ascertainable from the literature.

### 7.1 Operative risks

The immediate operative risks to the donor can be stated with some certainty. In one study, risk of life-threatening or permanently disabling complications was 0.23%. Complications of donor nephrectomy include pulmonary embolism, pneumothorax and myocardial infarction. Less serious complications were 8% in one series of 871 donors consisting of: wound infection (2.4%), unexplained fever (0.9%), pneumonia (0.9%) wound hematoma (0.6%) and urinary tract infection (0.3%).<sup>1</sup>

### 7.2 Long term risks

The long-term effects of donor nephrectomy are not completely understood. Follow up of renal donors generally provides 20-year data and, at most, 30-year data. Since donors are accepted from 18 years onwards, ongoing studies of donors will be necessary until 50 and 60 year follow up data become available.<sup>1</sup>

There are two possible issues in relation to long-term risk. First, there is concern that the donation per se will cause renal failure. However, most long term follow up studies of living kidney donors find no decrease in long-term survival.<sup>1, 16</sup> One German study indicated that no kidney donors surveyed developed marked renal insufficiency up to 19.8 years after donation.<sup>17</sup> One study with a 25 year follow up showed that renal function is well preserved in donors.<sup>18</sup> The longest follow-up of people after a single nephrectomy is a 45 year follow-up of WWII veterans. Their survival rate was similar to other veterans.<sup>1</sup>

Second, there may be concern that donors who develop primary renal disease will progress to renal failure more quickly because they have lower than normal renal mass at the onset of the primary renal disease. The latter concern applies particularly to patients with a family history that puts them at risk for renal diseases. However, a number of long term studies indicate that kidney donors do not seem to be at risk for developing hypertensive disorders more often than the general population,<sup>17</sup> although other studies state that it is unclear whether hypertension is more common in donors than in the general population.<sup>1</sup> In the above study with a 19.8 year follow up, there was an indication of some subclinical hyper filtration damage of the glomerulus, but there was no evidence of progressive renal insufficiency with clinically relevant function loss.<sup>17</sup> However, there have been cases of donors developing end stage renal disease, with a least 6 case reports in the literature of renal failure after donation, leading the authors of one survey of the literature to estimate the frequency of end stage renal disease after donation at 0.1%.<sup>1</sup>

Having a single kidney is not a contraindication to pregnancy.<sup>1</sup>

### 7.3 Risk disclosure

All living, directed donors in NSW are provided with detailed explanation of the risks by their referring nephrologist and the transplanting surgeon. This is supplemented by a standard information package available to all centres in NSW containing written material and a video presentation.

## **8. Ethical and other issues related to living, directed kidney donation**

Directed donation is generally considered ethically acceptable because of the close connection between the donor and the recipient. However, this very closeness may generate concerns about donor voluntariness in directed donations. In short, can closeness also be a risk?

A number of situations may raise concerns including:

- Where there appears to be an unbalanced relationship between a “needy” recipient who is constantly and unilaterally dependent on a “helpful” donor.
- Where a donor may have unrealistic expectations for the recipient after the transplant. Unrealistic expectations coupled with a poor medical outcome may impose a heavy burden on the donor-recipient relationship.<sup>19</sup>
- Where there are doubts about voluntariness in a donor who appears from interstate or overseas, possibly as a distant relative or ‘new friend’.
- Where there is a conflicted donor-recipient relationship that may mean that the recipient experiences the donation as a ‘burden’ to them, rather than a gift.<sup>19</sup>

***Issues for consideration:***

- **What, if any, limitations should be placed on directed donation?**
- **What psychosocial assessment of donors and recipients is appropriate? (see 9.3 on p.9)**

## **9. Ethical and other issues related to living, non-directed kidney donation**

In relation to directed donations, the morally significant relationship between the donor and recipient is generally considered sufficient to justify the bodily intervention inflicted on the donor. However, is such an intervention justified where the recipient is a stranger?

### 9.1 Autonomy and paternalism

Society has long tolerated the right of an individual to make decisions about engaging in risky behaviour. Society endorses as ethically commendable, activities which can place an individual at a reasonable level of risk, if the activity can rescue other people, including strangers, from danger, for example, volunteer fire fighting, surf life saving etc. Indeed, risky behaviour may be considered acceptable, even when its only purpose is pleasure and recreation.

Given that autonomy in these activities is acceptable and ethically desirable, any rejection of non-directed kidney donation warrants an examination of why the principle of autonomy should not be upheld in respect of a potential donor’s decision.

The often-quoted distinction is that organ donation is a procedure undertaken upon a person by a physician thereby making the physician an “accomplice” in the risk taking behaviour. The physician may feel a moral responsibility towards the individual, greater than that the individual feels towards him or herself. The



















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