

ETHICAL ISSUES relating to access to organ transplantation: NEAC REPORT TO THE ASSOCIATE MINISTER OF HEALTH, 20 January 2015

# Executive summary

1. The National Advisory Committee on Health and Disability Support Services Ethics (NEAC) has undertaken work on access to organ transplantation. Organ transplants save lives and significantly improve health outcomes but there are not enough organs for everyone who needs one. It is essential that the processes for determining who receives an organ are fair, transparent and robust.
2. NEAC’s work has explored the processes for referrals, being placed on the deceased donor waiting list and deciding who receives an organ when one becomes available.
3. We have identified issues associated with:
	* + equity of access to transplantation (both living and deceased donor operations)
		+ application of ethical principles to the processes for listing patients and allocating deceased donor organs
		+ deceased donor list numbers for kidney transplants.
4. NEAC recommends that you:
	* + direct the Ministry of Health to lead work to better understand the clinical and non-clinical factors that influence patient access to transplants
		+ agree that NEAC lead work on how ethical principles are given effect through the decision-making processes for deceased donor transplants, following completion of the Australian National Health and Medical Research Council’s work on *Ethical Guidelines for Eligibility Criteria and Allocation Protocols for Organ Transplantation from Deceased Donors*
		+ direct the Ministry of Health to advise how best to progress work on the way waiting lists for kidneys are managed and the ethical implications of the possible problem of ‘false hope’
		+ agree that any future work should involve patients, health sector stakeholders and the wider public.

# Background

*NEAC’s work on access to organ transplantation*

1. In April 2013, NEAC commenced work on the ethical issues associated with access to organ transplantation (involving organs from living and deceased donors). Organ transplants save lives and significantly improve health outcomes but there are not enough organs for everyone who needs one. Given this, NEAC considered that it was important to review the processes for determining who receives an organ and assess whether they were fair, transparent and robust.
2. NEAC met with several transplant units and other interested parties to discuss current processes for deciding who gets an organ and identify any associated issues (see Appendix 1 for a list of those consulted). We were particularly interested in the processes for:
* referrals
* being placed on the deceased donor waiting list
* deciding who receives an organ when one becomes available.
1. NEAC informed the previous Minister of Health about its work on access to organ transplantation in February 2014 [NEAC Report 20140333 refers]. The previous Minister agreed that NEAC’s initial work in this area should continue.
2. In September 2014, NEAC provided an early draft of this report to stakeholders and received well-considered and detailed comments and suggestions. Several stakeholders raised ethical issues associated with organ donation and other aspects of transplantation (eg, paired kidney exchange scheme)[[1]](#footnote-1) but these were not within the scope of NEAC’s work. In general, stakeholders were supportive of NEAC’s work and several expressed an interest in any future work.

Overview of transplants in New Zealand

1. In order to be considered for an organ transplant (involving either a deceased or living donor), patients need to be referred by their GP to a consultant, who then makes a referral to the transplant unit. All patients are required to undergo medical and psychosocial tests to assess their suitability for transplant.
2. Patients may then be placed on the deceased donor list.[[2]](#footnote-2) The criteria for being placed on the list differ for each organ. When a deceased donor organ becomes available, a range of criteria are taken into account in deciding who receives the organ, for example, blood group, size of the organ relative to the size of the patient being transplanted, and urgency.
3. Liver, heart, pancreas[[3]](#footnote-3) and lung transplants are each performed at a separate transplant centre, all of which are located in Auckland. There is one national waiting list for each of these organs. Kidney transplants are performed in Auckland, Wellington and Christchurch. There is one national waiting list for all patients awaiting deceased donor kidney transplants. Deceased donor kidneys are allocated to patients on that list, with the operation occurring at the centre where the patient has been accepted onto the list.
4. Table 1 shows the number of transplants performed in New Zealand each year.

### Table 1: Number of transplants performed each year

| **Transplanted organ** | **2009** | **2010** | **2011** | **2012** | **2013** |
| --- | --- | --- | --- | --- | --- |
| Hearts | 11 | 11 | 11 | 12 | 9 |
| Lungs | 8 | 9 | 10 | 12 | 19 |
| Livers (deceased donors) | 31 | 35 | 36 | 29 | 31 |
| Livers (living donors) | 8 | 6 | 8 | 3 | 3 |
| Pancreas | 2 | 3 | 3 | 2 | 1 |
| Kidneys (deceased donors) | 54 | 50 | 61 | 54 | 55 |
| Kidneys (living donors) | 67 | 60 | 57 | 54 | 58 |

Source: Organ Donation New Zealand

# ADVICE

1. NEAC’s analysis has identified issues with:
* equity of access to living and deceased donor transplantation
* application of ethical principles to the processes for listing patients and allocating deceased donor organs
* deceased donor list numbers for kidney transplants.
1. These issues are outlined below, along with current responses and recommendations for further work.

## Equity of access

*Issues*

1. NEAC considers that people may be treated differently in referral and assessment processes, and when receiving an organ transplant or being placed on the deceased donor waiting list. The extent of the unequal treatment may differ depending on the organ involved.
2. Literature suggests that Māori and Pacific peoples are less likely to receive a transplant compared to New Zealand European.[[4]](#footnote-4),[[5]](#footnote-5) This situation is not limited to New Zealand; indigenous patients are less likely to receive transplants in other western countries, such as Canada, Australia and the United States.[[6]](#footnote-6)
3. Recent data from the New Zealand Lung Transplant Service suggests that access is improving, at least for Māori. Seven of the 15 lung transplant recipients in 2014 (up to October 2014) were Māori, compared with 14% of all lung transplant recipients since the inception of the Service in March 1993.
4. A higher prevalence of co-morbidities may partly explain ethnic differences. Other factors that could influence access include:
* delays in referral from a GP to a specialist to determine suitability for transplant
* delays from initial referral to seeing a specialist and being placed on the waiting list
* communication between doctors and patients
* health literacy
* regional variability in gaining access to tests; some tests can only be done in the main centres or by a visiting physician
* logistics and resource issues eg, transport issues for patients living in remote areas, lack of theatre or surgeon time, or prioritising other surgery over living donor organ transplants (deceased donor transplants are emergency operations).

*Current response*

1. Current Ministry of Health initiatives aim to address barriers to live kidney donation through improving communication and support for patients and families, and increasing consistency across District Health Boards (DHBs).
* A pilot programme in Counties-Manukau DHB aims to increase the number of live kidney donors through new educational resources and community-based family educators.
* Live Kidney Donation Aotearoa[[7]](#footnote-7) has developed resources, with input from all services involved in kidney donation and transplantation, for patients considering a live kidney transplant. These aim to be clear, informative and accessible to anyone.
* The new National Renal Transplant Service aims to better co-ordinate transplantation services across the country and increase transplant numbers.
1. Transplant units make considerable efforts to produce resources, both written and verbal, for patients. These resources are aimed at improving health literacy, a factor implicated in unequal access.

*Recommendations*

1. There is a lack of clarity on the reasons for differential access and the relative importance of various factors (discussed in paragraph 18). As a result, initiatives aimed at improving access to transplants may be poorly targeted and less effective.
2. NEAC recommends that you direct the Ministry of Health to lead work to better understand the clinical and non-clinical factors that influence patient access to transplants. It may also be worth exploring how regional variability and logistics/resource issues affect access.

## Application of ethical principles to deceased donor transplants

1. Decisions on whether to list someone and who to allocate an organ to are based on the three ethical principles of outcome, need/urgency and equity. To make the best possible use of the small number of deceased donor organs available relative to demand, recipients need to be sick enough to need an organ transplant, but also have a good chance of achieving a successful outcome. Further, there should be no discrimination between potential recipients on the basis of anything other than established eligibility criteria.
2. These ethical principles are given effect by the decision-making process that clinicians follow. There are three main aspects to this process:[[8]](#footnote-8)
	* + criteria
		+ clinical judgement
		+ weighting given to each criterion.
3. These three areas are discussed below:

Criteria

1. Many inclusion and exclusion criteria are used to determine whether to list a patient for transplant and to decide who receives an available organ. The criteria used differ between organs.

*When deciding whether to list a patient, criteria include:*

* + - lack of exclusionary co-morbidities
		- no active substance abuse
		- likely adherence and ability to comply with complex medical treatment
		- likelihood of survival for 5 years post-transplant – different percentages are used for different organs (eg, 80% for kidneys, 50% for livers)
		- age – while age in itself is not a criterion, advancing age generally means there are co-morbidities that will exclude the patient from being listed. Additionally, children are prioritised for kidney transplants.

*When allocating an organ, criteria include:*

* + - blood type
		- size of organ relative to the size of the patient being transplanted
		- Human Leukocyte Antigen (HLA) matching (kidneys only) – where there is a patient who is closely matched to an available deceased donor organ, they receive additional priority (due to better outcomes). Approximately 30% of deceased donor kidneys are allocated to patients with a close match.

Clinical judgement

1. Objective criteria provide less opportunity for gaming of the system and can be seen as an impartial way of allocating a scarce resource. However, using only objective criteria may mean there is insufficient flexibility in certain circumstances to determine the best use of the resource. Therefore clinical judgement is used alongside the objective criteria.
2. Clinical judgement, based on the clinician’s experience and not just test results, is used throughout the listing and allocation process. For example:
	* + when determining a patient’s likelihood of survival, based on, among other factors, their likely level of compliance with post-transplant treatment
		+ where there is a marginal organ that may not be suitable for a very sick patient, but may be suitable for someone lower down on the waiting list
		+ where there is a liver that can be split and used for both a child and an adult.

Weighting of criteria

1. As clinicians apply various objective criteria in combination with clinical judgement, this indicates a weighting exercise is occurring at each stage of the process. In other words, clinicians may place more importance on some objective criteria than others. It is unclear whether the weighting is consistently applied between patients.

*Issues*

1. NEAC’s primary interest is in how the ethical principles (outcome, need/urgency and equity) are given effect in deceased donor transplant decisions. As John McCall succinctly stated in his feedback:[[9]](#footnote-9) the fundamental issue here is the interplay between information that is essentially technical and highly specialised in nature and the application of ethical principles.
2. It is important that the criteria used to give effect to the ethical principles are valid and sensitive enough to distinguish between, for example, poor and good outcomes. The relative weight given to each criterion also needs to be commensurate with its value as a proxy for the ethical principles and relative importance compared with other measures.
3. NEAC’s work has identified several issues relating to the criteria:
* It is unclear how the different cut-offs for likelihood of 5-year survival were arrived at or why the percentage is different between organs.
* Children are prioritised for transplants, sometimes to the equivalent of years on the waiting list, for no clear publicly stated clinical or ethical reason. However, there does not appear to be any priority for younger adults compared with older adults.
* HLA matching is used as a criterion for kidney transplants; however, the difference in survival for a very well matched kidney versus a poorly matched kidney is only 5-10%.
* It is unclear how the competing principles of outcome, need/urgency and equity are being weighed against each other.
1. Clinical judgement will vary between clinicians, and between types of organ. To ensure equal access, clinicians need to ensure that their decisions are consistent between patients, and with other clinicians. Transplant units make decisions as a team and this can help ensure decisions are consistent.
2. Decisions about who gets on the waiting list and who gets an organ when one becomes available must be clinically informed. However, the weight given to different criteria needs to reflect clearly the supporting ethical principles. This is particularly important when there may be competing interests. For example, should an organ be allocated to someone who will live longer (outcome principle), but has been waiting a shorter time (justice principle)? Allocation decisions need to be ethically defensible as deceased donor (and non-directed living donor) organs are a community-held resource.

*Current response*

1. The Australian National Health and Medical Research Council, together with the Organ and Tissue Authority and TSANZ, are developing *Ethical Guidelines for Eligibility Criteria and Allocation Protocols for Organ Transplantation from Deceased Donors*. An Expert Advisory Group will consider such issues as likelihood of survival as an eligibility criterion for entry onto waiting lists, and the balance of criteria relating to utility and equity for entry onto waiting lists and determining transplant recipients. The Expert Advisory Group’s term runs until 30 June 2015.
2. New Zealand clinicians are not directly involved in this work but they are involved in TSANZ which is contributing expertise to the process.

*Recommendations*

1. NEAC recommends that you agree that NEAC lead work on how ethical principles are given effect through the decision-making processes for deceased donor transplants, including how best to make decisions when ethical principles come into conflict. Stakeholders broadly support this recommendation.
2. This work could also consider how best to take account of the value patients place on outcomes. For example, a patient may regard a kidney transplant as worthwhile even if it only lasts a year or two because it gets them off dialysis, whereas a clinician may view this as a poor outcome.
3. NEAC considers that public views are important for this area. As deceased donor organs are a community-held resource, the public should have the opportunity to contribute to the development of guidelines on relevant ethical principles and their application in transplant decisions. NEAC recognises that there are likely to be disparate views on what factors should be taken into account and that some public views may be at odds with the views of other stakeholders, such as clinicians. However, we consider it is important that all views are heard.
4. Public engagement in developing guidelines may increase buy-in and trust through a shared understanding of how decisions are made. This may increase organ donation in the future.
5. NEAC considers that it is well-placed to undertake this work given the ethical nature of the issues and its experience in gathering community views. If you agree to NEAC undertaking further work, we suggest that this work is started once the Australian work on ethical guidelines is completed. This would mean that NEAC’s work could be informed by the results of this work, and focus on the Australian guideline’s application in the New Zealand context.

## Deceased donor list numbers

1. There are more people on the deceased donor waiting lists than there are organs available and some people will never get an organ.
2. The nature of end-stage heart or lung disease means that patients who need new organs will usually not live long without them. The waiting lists for hearts and lungs run only slightly higher than the number of organs transplanted each year. The median waiting time for a lung transplant is 18 months. The New Zealand Lung Transplant unit does not place people on the active waiting list who they do not believe will live to transplant; however deaths do occur while awaiting transplant.
3. Patients with kidney failure have an option of dialysis, often for long periods; therefore they are able to remain on the list for a longer time than other organs. There are approximately 600 people on the waiting list for a kidney, about 170 patients are added to the list each year and transplants are performed for about 110 (using living and deceased donor organs). A significant minority will never have been on the deceased donor list because they have been able to find a suitable living donor (before being considered for the list).
4. The rate at which patients are added to the deceased donor kidney list is less than the transplant rate in several countries now, including Australia. Over time this is likely to result in a reduction in waiting list numbers. In New Zealand, there is currently no attempt to match the number added to the list to the number of transplants. We have been advised that, in the case of kidneys, this is because patients can remain on dialysis while they wait.
5. The average wait time from the start of dialysis to receiving a deceased donor kidney is three years, but many on the list will never receive a kidney (eg, due to death prior to transplant, or removal from the list due to a new co-morbidity). It is possible that some people of the waiting list may not realise that they have very low chances of being transplanted. Some stakeholders have raised an ethical issue of whether these people live in ‘false hope’.

*Recommendation*

1. NEAC recommends that you direct the Ministry of Health to advise how best to progress work on the way waiting lists for kidneys are managed and the ethical implications of ‘false hope’. Patient views will form an important part of this work as it is not clear whether the current situation is even a concern.

## Conclusions

1. Organ transplantation is an ethically-challenging subject. NEAC’s initial work suggests that the decisions made, and the basis behind these decisions, may not be as transparent and consistent as they could be.
2. NEAC recommends three areas for further work: examining the factors that contribute to unequal access; the application of ethical principles; and how deceased donor list numbers for kidneys are managed.
3. NEAC’s findings are indicative rather than definitive because of the limited consultation to date. NEAC has not consulted with patients, health sector stakeholders beyond those listed in Appendix 1, or the wider public.
4. NEAC suggests that involving the public in any future work may help to increase the rates of organ donation through increased buy-in.

# Appendix 1: Consulted parties

NEAC met with representatives from the following organisations and groups:

* Dunedin School of Medicine, University of Otago
* Māori Health, Auckland and Waitemata DHBs
* Department of Nephrology, Christchurch Hospital
* Auckland Renal Transplant Group, Auckland City Hospital
* New Zealand Heart and Lung Transplant Service
* New Zealand Liver Transplant Unit
* Sector Capability and Implementation, Ministry of Health
* National Renal Advisory Board
1. New Zealand’s Paired Kidney Exchange Scheme allows living donor/recipient pairs, where there is a Human Leukocyte Antigen and blood-grouping mismatch, the opportunity to exchange a kidney with others in a similar position. [↑](#footnote-ref-1)
2. Organs from non-directed living donors (donors who do not donate to a specific person) are also allocated to patients on the deceased donor list. [↑](#footnote-ref-2)
3. Auckland perform simultaneous kidney and pancreas transplants where the recipient has a condition that results in a non-functioning pancreas eg, type 1 diabetes. Generally, pancreas-only transplants are not performed in New Zealand as the benefits of a new pancreas do not outweigh the side-effects from the required immunosuppressants. [↑](#footnote-ref-3)
4. McDonald, S.P. (2013). End-stage kidney disease among indigenous peoples of Australia and New Zealand. *Kidney International Supplements*, 3, pp 170-173. [↑](#footnote-ref-4)
5. Yeates, K.E. *et al.* (2009).Indigenous people in Australia, Canada, New Zealand and the United States are less likely to receive renal transplantation. *Kidney International*, 76, pp 659-664. [↑](#footnote-ref-5)
6. *Ibid.* [↑](#footnote-ref-6)
7. Live Kidney Donation Aotearoa is a programme that is coordinated by kidney health practitioners and scientists with strong links to community and other stakeholders in the field of kidney disease. The programme works directly with patients and their whānau, the Ministry of Health, community groups, health practitioners (including GPs) and Counties Manukau Health. [↑](#footnote-ref-7)
8. These aspects are set out in guidelines. Heart, liver, kidney and pancreas transplantations mainly follow the Transplantation Society of Australia and New Zealand (TSANZ) consensus statement on eligibility criteria and allocation protocols for organ transplantation from deceased donors. However, the New Zealand Lung Transplant Service uses the International Society for Heart and Lung Transplantation (ISHLT) guidelines. [↑](#footnote-ref-8)
9. John McCall, comments on NEAC’s draft report, 13 October 2014 [↑](#footnote-ref-9)