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The Transplantation Society of Australia and New Zealand.

National Protocol for Organ Transplantation

Eligibility and Allocation Criteria

Draft for Public Consultation

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Disclaimer

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Introduction

Cadaveric organ transplantation (heart, lung, liver, pancreas and kidney) is a highly effective treatment for advanced organ disease; however its use is limited by the scarcity of suitable donor organs. The donation of organs is an act of altruism and human solidarity that potentially benefits those in medical need and society as a whole.¹ Organ transplantation relies on the donation of organs from living or deceased donors. Currently the number of patients who may benefit from transplantation is far greater than the number of organs donated. For this reason, cadaveric organ transplantation is offered primarily to patients who have end-stage organ disease and who have exhausted all alternative treatment options. As such, protocols have been developed to ensure there are equitable and transparent criteria for listing patients for organ transplantation, and to ensure consistency across Australia in the criteria by which donated organs are allocated.

Central to these eligibility and allocation protocols are the following ethical principles which were embodied in the National Health and Medical Research Council's (NHMRC) publication *Organ and Tissue Donation After Death, for Transplantation, Guidelines for Ethical Practice for Health Professionals*.¹

- Organs and tissues will be allocated fairly, following specific processes for each type of organ or tissue as well as criteria for matching the donation to the recipient.
- Allocation decisions will not be made on the basis of race, religion, gender, marital status, sexual orientation, social status, disability or age (except where age may affect the outcome).

To be eligible to be listed for organ transplantation, patients must meet the eligibility criteria outlined in this protocol. In the case of heart and kidney disease, this includes patients whose survival is dependent on mechanical circulatory support and dialysis respectively, although not all of these patients will be potential candidates for organ transplantation. The assessment process requires patients to be evaluated by a transplant unit; during this process the evaluation takes into consideration the patient's medical history and other relevant factors to ensure that they are suitable for transplantation. Once listed for transplantation, patients should be regularly reviewed by the transplant unit to ensure that they are fit for organ transplantation. Patients, once listed, may be removed from the transplant list if their condition changes, which could either be improvement or deterioration to the point where they no longer meet the eligibility or allocation criteria outlined in this protocol.

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Transplantation is a highly successful treatment and Australia is a world leader in clinical outcomes for transplant patients.² The allocation process involves the transplantation units making a clinical judgement when an organ becomes available as to which patient on the transplant list is most appropriate to receive that particular organ, at that particular time, based on a range of factors. The allocation of organs is a complex process; a number of factors influence the allocation process including medical need, medical urgency, capacity to benefit, donor/recipient matching and logistical factors. The donor organ is matched to a particular recipient on the organ transplant list, with the aim of maximising the likelihood of a successful outcome. The allocation process and criteria vary depending on the type of organ to be transplanted, as outlined in this protocol.

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Heart

Heart Transplantation Eligibility and Allocation Criteria

Introduction

Heart transplantation is a highly effective treatment for advanced heart disease, however its use is limited by the scarcity of suitable donor organs.^{3, 4} For this reason, heart transplantation is offered only to patients who have end-stage heart disease and who have exhausted all alternative treatment options.^{5, 6} This includes patients whose survival is dependent on mechanical circulatory support, although not all of these patients will be potential candidates for organ transplantation. The median post-transplant survival for patients undergoing heart transplantation in Australia or New Zealand is approximately 14 years.⁷ A decision to offer transplantation should be based on the expectation of low peri-operative mortality, a post-operative life expectancy of at least 10 years and reasonable prospect of returning to an active life-style.^{5, 6}

Currently recognised Heart Transplant Units

New South Wales	St Vincent's Hospital
Queensland	Prince Charles Hospital
Victoria	The Alfred Hospital
	Royal Children's Hospital (Paediatric)
Western Australia	Royal Perth Hospital
New Zealand	Auckland City Hospital

Comment [MSOffice1]: Tables amended after the release of the draft document due to publishing error

Inclusion Criteria

1. End-stage heart disease may be manifested as:

1. Cardiogenic shock e.g., complicating acute myocardial infarction
2. Intractable symptomatic heart failure (NYHA Class III-IV) despite maximally tolerated evidence-based medical therapy.
3. Need for permanent mechanical cardiac support
4. Frequent repeated discharges from an implanted AICD device
5. Intractable angina despite optimal medical, interventional and surgical treatment

Exclusion Criteria

Exclusion criteria include any condition or combination of conditions which result in an expected 10 year survival after transplantation of less than 50% or which precludes active rehabilitation after transplantation.⁵⁻⁸ Although chronological age is not by itself an exclusion criterion, the presence of multiple co-morbidities in patients more than 65 years of age would be expected to exclude the majority of such patients from consideration.^{5,6}

Exclusion criteria include but are not limited to:

1. Active malignancy.⁵
2. Irreversible dysfunction of other organs or combined organ transplant (e.g., heart/lung, heart/kidney, heart/liver) may be a consideration.^{3,9-12}
3. Complicated diabetes.⁸
4. Irreversible degeneration/damage of other organ systems that precludes rehabilitation after heart transplantation e.g., advanced neurodegenerative disease, advanced rheumatoid arthritis, severe peripheral vascular disease not amenable to revascularisation.^{5,6}
5. Uncontrolled infection.
6. Morbid obesity (BMI > 35 or >140% ideal body weight).^{13,14}
7. Inability to comply with complex medical therapy e.g., chronic cognitive or neuropsychiatric deficits in the absence of a carer capable of taking on this role.^{15,16}
8. Active substance abuse including smoking, alcohol and illicit drug use.¹⁷⁻¹⁹
For individuals with a history of substance abuse, a period of 6 months abstinence is recommended (with confirmatory blood testing if considered appropriate) before active listing is considered.²⁰

Relative contra-indications to heart transplantation include uraemia with calculated (or measured) glomerular filtration rate (GFR) < 40 ml/min,^{7,21} hyper-bilirubinaemia > 50 µmol/L, intractable ascites with hypoalbuminaemia¹² and fixed pulmonary hypertension with trans-pulmonary gradient (TPG) > 15 mmHg or pulmonary vascular resistance (PVR) > 4 Woods Units after pulmonary vasodilator challenge.²¹ These clinical characteristics identify individuals with a marked increase in post-transplant mortality regardless of whether there is evidence of intrinsic kidney, liver or lung disease.^{7,12,21} Patients with evidence of renal and/or hepatic decompensation who otherwise meet eligibility criteria for heart transplantation should be considered for mechanical circulatory support, so called 'bridge to decision'.^{22,23} Similarly, patients with fixed pulmonary hypertension should be considered for heterotopic heart transplantation (see below) or long-term mechanical circulatory support which has been shown to reverse pulmonary hypertension over a 3 to 6 month period in a large proportion of patients.^{24,25}

Special Circumstances/Considerations

Heterotopic Heart Transplantation

Historically, the vast majority of heart transplants have been performed orthotopically.

Heterotopic heart transplantation may be considered in two clinical settings:

1. Patients who meet the above criteria for heart transplantation and who have fixed pulmonary hypertension as evidenced by a transpulmonary gradient > 15 mmHg after vasodilator challenge.²⁶ Paediatric patients with a high pulmonary vascular resistance may be considered for orthotopic transplantation, based on the presence of acute reactivity, expected regression post-transplantation, the magnitude of the peri-operative risk and the availability of other treatment options.
2. Extended criteria donor in which donor heart function is judged to be suboptimal for orthotopic transplantation (but potentially recoverable) may be considered for heterotopic transplantation subject to informed consent of the potential recipient.²⁷

Combined Organ Transplantation (Heart/Lung, Heart/Liver, Heart/Kidney)

Combined organ transplantation can be carried out with the expectation of a similarly low peri-operative mortality and reasonable life expectancy as heart-alone transplantation *in carefully selected individuals*.⁹⁻¹¹ Patients being considered for combined heart/other organ transplantation need to meet all standard criteria for heart transplantation plus

1. have evidence of advanced irreversible dysfunction of the other organ and meet standard criteria for transplantation of that organ e.g., Eisenmenger Syndrome secondary to complex congenital heart disease (heart-lung transplantation), end-stage renal failure (heart-kidney transplantation).
2. have evidence that heart transplantation alone will result in a poor life expectancy unless the other organ is also transplanted e.g., combined heart-liver transplantation for end-stage ischaemic heart disease in association with homozygous hypercholesterolaemia or cardiac amyloidosis in association with familial autonomic neuropathy.

Evaluation of patients for combined organ transplantation requires detailed assessment and agreement by both organ transplant teams that the patient meets eligibility criteria.

The decision to allocate cadaveric organs for combined transplantation needs to take into consideration the implications for individuals who are on waiting lists for single organs.

Heart retransplantation

Recent data from the registry of the International Society for Heart & Lung Transplantation indicate that *carefully selected patients* undergoing cardiac retransplantation following irreversible failure of the initial cardiac allograft can achieve excellent short- and long-term survival, although still less than what can be expected for a patient receiving a first cardiac allograft.⁴ The decision to accept a patient for retransplantation must take into account both the survival prospects of the recipient and the potential implications for other individuals who are on the waiting list for heart transplantation.

International patients

TSANZ endorses the Declaration of Istanbul on organ trafficking and transplant tourism.^{28, 29} In view of the existing gap between heart donors and recipients, TSANZ considers it inappropriate for international patients to be assessed for possible heart transplantation, except under the following circumstances:

- (i) when the patient comes from countries with reciprocal Medicare arrangements with Australia.
- (ii) when an international visitor on a tourist or work visa develops acute severe heart failure that would normally warrant consideration for heart transplantation and is too unwell to return to their home country. Under these circumstances it needs to be established that the visitor did not have pre-existing heart disease requiring consideration for heart transplantation prior to their travel to Australia and that the visitor will return to an environment that permits appropriate ongoing post-transplant surveillance and treatment.

Donor Heart Allocation

Organ Donors' Suitability Criteria

Standard Criteria

1. General Organ Donor Criteria
2. Age to 50 years
3. No known significant cardiac disease (if in doubt contact heart transplant unit)
4. Not dependent upon high dose inotropes (noradrenaline < 0.2 ug/kg/min or equivalent)

Extended criteria donors (donor characteristics that are associated with increased short and/or long-term morbidity and mortality after heart transplantation):

1. Donor age between 50 and 60 years. There is a progressive increase in the risk of death after heart transplantation as the donor age rises above 30 years. A donor age of 50 years is associated with a 50% increase in the relative risk of death at one year post-heart transplant compared with a donor aged 30 years. The relative risk of death at one year post-transplant rises to 80% at a donor age of 60 years.²¹
2. Anticipated ischaemic time > 360 minutes. There is a progressive increase in the risk of death after heart transplantation as the donor heart ischaemic time increases above 240 minutes. Donor heart ischaemic time > 360 minutes is associated with a 30% increase in the relative risk of death at one year post-heart transplant.²¹
3. Donor requiring high-dose inotropic support.³⁰
4. Donor graft dysfunction on Echo (LVEF < 50%, major wall motion abnormality, LVH > 13 mm*).^{31,32}
5. Donor co-morbidities ó e.g., Donor positive for Hep B or Hep C.^{32,33}

* Although donor left ventricular hypertrophy (LVH) has been considered a relative contra-indication to heart transplantation, more recent experience suggests that these hearts can be used with similar outcomes to hearts without LVH.³⁴

Utilisation of extended criteria donors is at the discretion of the heart transplant unit. Allocation should be based on the same principles as standard criteria donors.

Required Information for allocation

1. Blood group
2. Body weight
3. Body height
4. Laboratory tests - General Organ Donor Criteria for viral studies
HIV, HepBsAg, HepBcab, Hep C, CMV
5. Investigations - Current chest X-ray the ECG done after brain death
- Echocardiogram is desirable

Organ Retrieval Mechanism

The unit accepting the heart offer is responsible for arranging the surgical procedure either using a team from their hospital or by arrangement with another appropriate team from one of the other recognised heart transplant units.

The unit accepting the heart offer is responsible for liaison with the relevant donor co-ordinator to achieve a surgical starting time mutually acceptable to the donor hospital and all involved donor surgical teams.

The unit accepting the heart offer is responsible for ensuring that the heart, and if retrieved the lungs, meet medical standards for organ donation and are delivered in a safe and appropriate manner to the recipient unit's hospital.

Organ Allocation and Distribution

The recognised Heart Transplant Unit in the state of the donor's hospital is offered the donation as detailed below. They have 20 minutes to respond to the offer.

State of Donor Hospital	Heart Transplant Unit
New South Wales/ACT	New South Wales
Queensland	Queensland
Victoria/Tasmania	Victoria
Western Australia	Western Australia

If the home state declines the offer, then the heart donation offer is made to the non-home state recognised heart transplant units, with a 20 minute response time. In Victoria the donor co-ordinators keep a record of the rotation between the 2 units. The non-home state offer is based upon a rotation kept by each state donor co-ordination

team, such that the first non-home state offer is rotated through each state in strict turn. If the first non-home state declines the offer, the next is asked until all units have been asked. Donor heart offers from South Australia and the Northern Territory will be offered on the same rotation as for non-home state offers.

New Zealand organ donor offers

New Zealand heart donor offers that are declined by the New Zealand Heart Transplant Unit may be offered by New Zealand to the Eastern State recognised Heart Transplant Units. The rotation of offers to those units is held by the New Zealand Donor Co-ordinators.

Individual Patient Allocation

Donor hearts will be allocated according to the following criteria:

1. ABO compatibility*
except paediatric patients aged less than 12 months.³⁵
2. Negative lymphocytotoxic crossmatch*
Sensitised paediatric recipients for whom there are no other options may require transplantation in the setting of a positive T and B cell cross-match, followed by augmented immune suppression.
3. Size & weight compatibility*
+/- 20 % of donor body weight*
Greater variability in the ratio of donor:recipient weight may be acceptable depending on the age of donor and recipient especially in paediatric cases.³⁶
4. Urgent Status**
5. ABO identity
6. Recipient Waiting Time
7. Logistics***

The decision about each individual offer and waiting list management are the responsibility of each recognised Heart Transplant Unit

Explanatory notes

* Items 1-3 are absolute requirements for adult patients.

** Urgent Status for Heart Transplantation

Most patients with heart failure that is so severe that it poses an immediate threat to life (e.g., cardiogenic shock) will be implanted with some form of mechanical device

(e.g., LVAD or BVAD) and rehabilitated prior to active listing for heart transplantation. Occasionally, such transplant candidates are unsuitable for mechanical support or develop life-threatening complications while on support e.g., severe sepsis or mechanical device failure. Under these circumstances, when the patient's survival is estimated to be days or weeks without transplantation, the patient may be placed on an Urgent List, in which case the next compatible donor heart arising anywhere in Australia and New Zealand will be offered for that individual.

Urgent listing for heart transplantation is at the discretion of the Transplant Unit Director. It will be the responsibility of the Transplant Unit Director (or his or her nominee) to notify all other Cardiothoracic Transplant Units in Australia and New Zealand, and to notify the organ donor co-ordinators in all jurisdictions when a patient is placed on (and removed from) the Urgent Waiting List.

It is expected that the majority of individuals placed on the Urgent Waiting List will either die or be transplanted within two weeks of notification. Each Transplant Unit will be allowed a maximum of 3 Urgent listings within any 12 month period. The operation of the Urgent Waiting List will be subject to annual audit and review by the Cardiac Standing Committee of TSANZ.

*** Logistical considerations include:

- Operation type (orthotopic, heterotopic or domino)
- Time of retrieval: operation room availability
- Location of recipients &/or donor: (local, interstate)
- Type (i.e. road or air) and availability of transport to bring recipient to the transplant centre and to take retrieval team to donor hospital
- Availability of required team members for the retrieval and transplant.
- Availability of I.C.U. beds
- Donor instability

It is recognised that logistical considerations may override criteria 4 through 6 (e.g., if there are transport problems that prevent the selected recipient from being transported to the transplant hospital in time). In instances where logistics override higher criteria, this needs to be recorded as well as the specific logistical issue e.g., transport.

Domino hearts

Domino hearts donated by a recipient of a heart/lung transplant should be donated according to the relevant jurisdictions' laws on living donation and allocated to a medically appropriate recipient in the waiting list of that Heart/Lung Transplant Unit.

Kidney

Kidney Transplantation Eligibility and Allocation Criteria

Introduction

It is established that the majority of patients with end stage kidney failure would feel healthier, live longer and have a better quality of life with a renal transplant, compared to staying on dialysis.³⁷⁻⁴⁰ However, the number of kidneys available for transplantation from deceased donors is far short of the number required to transplant all those who would want, and would benefit from, a kidney transplant.⁴¹ The number of transplants performed each year is determined by the number of kidneys available. It is not limited by the criteria by which patients enter the transplant list or the allocation algorithm. The allocation of cadaveric donor kidneys seeks to maximise the best balance between individual patient and societal needs while recognising in practice this is imperfect. All patients have the right to know whether or not they are on the active kidney transplant waiting list. All patients who are not on the transplant list have the right to know the reasons for this.

Renal Transplanting Units

New South Wales	Royal Prince Alfred Hospital Westmead Hospital
	Prince of Wales Hospital John Hunter Hospital
	Royal North Shore Hospital
Queensland	Queensland Renal Transplant Service (Princess Alexandra and Mater Children's Hospitals)
South Australia	Queen Elizabeth Hospital
Victoria	Royal Melbourne Hospital Monash Medical Centre Austin Health St Vincent's Health
	The Alfred Hospital
Western Australia	Royal Perth Hospital Sir Charles Gairdner Hospital

Inclusion Criteria

1. End stage kidney failure requiring dialysis

Exclusion Criteria

1. The decision to offer transplantation should be based on the expectation of low peri-operative mortality and a reasonable post-operative life expectancy of 80% at 5 years.⁴² Co-morbidities that might reduce the expectation of such an outcome include cardiac disease, vascular disease, diabetes mellitus and malignancies.⁴³⁻⁴⁶
2. Although advanced age in the absence of significant medical co-morbidity is not necessarily a contraindication for renal transplantation, fewer than 5% of the end stage kidney failure patients in Australia aged over 65 are currently listed for renal transplantation due to the presence of co-morbidities.
3. Similar outcomes should be expected for recipients receiving combined transplants, where a kidney is transplanted with another organ (liver, pancreas, heart).

Assessment and Acceptance Principles

- Referrals for Renal Transplantation (From Renal/Dialysis Units) should be assessed initially at the level of the Transplanting Hospital. This review and a decision regarding acceptance for listing should involve a transplant physician and surgeon.
- The Transplant Unit should have a system to allow borderline candidates to be assessed by a broader group of transplant specialists.
- Each state should have a second-tier review committee (the structure of which may vary between states) to review cases where requested.
- Reassessment of patients on the waiting list should occur at least annually by the Transplant Unit. Usually this would be in person. Transplant Units will have a process to formally ensure ongoing suitability.
- Only the Director of a Transplanting Unit (or their delegates) will have the authority to have patients added to the active renal transplant waiting list.

Donor Kidney Allocation

Introduction

The allocation of kidneys from a deceased donor to patients on the transplantation list is determined by a computer program called the National Organ Matching System or NOMS. NOMS is administered by the Australian Red Cross Blood Service. In most cases, only patients who have commenced dialysis will be eligible to be listed on the transplantation list.

The major criteria that are used by NOMS to decide which patient on the transplant list will be allocated the kidney are:

- The blood group (most kidneys go to somebody who is the same blood group as the donor).
- How long the patient has been on dialysis.
- The Tissue Typing or matching with the donor.
- Whether the patient has a lot of antibodies against other people's tissue types.
- Whether the patient is a child, as paediatric patients get priority.

Allocation Principles

- The rules for each state's allocation protocols should be transparent and available to all potential recipients.
- At least 30% of all locally allocated kidneys should be allocated according to waiting time (rather than HLA matching).
- Each transplanting region should have a mechanism to review its list annually, and to implement policies that minimise the percentage of patients waiting more than 5 years for their first cadaveric donor kidney.
- Patients who are under the age of 18 years, and who have been on dialysis for more than 12 months will be eligible for paediatric prioritisation on the State-based Transplant Waiting List. This prioritisation will make them eligible for the next standard criteria donor of the same blood group.
- A Hepatitis C Positive Register exists to allow transparent and equitable allocation of kidneys from Hepatitis C positive donors to Hepatitis C positive recipients for units that undertake these operations.
- It is anticipated that the medical quality of donated kidneys will continue to fall, as more kidneys are received from older donors with greater numbers of medical problems. This poses questions about how to most fairly utilise these kidneys, while trying to also maximise the outcomes for all transplanted kidneys.
- Renal Transplant Advisory Committee (RTAC) is exploring a local definition for Extended Criteria Donors, which might encompass approximately the

worst 10% of kidneys. Consideration will be given to whether these should be allocated in a different way, recognising that the likely graft survival will be poorer than from standard criteria kidney.

National Interstate Exchange Program

NOMS database runs a national matching program, which looks at all of the patients that are waiting in Australia to mainly identify patients who have a lot of antibodies against other people's tissue types. This is important because these patients really need a very well matched kidney to ensure a good outcome. It is much harder to find a suitable kidney for these patients, than for patients who do not have these antibodies. If a patient with a lot of antibodies is identified in NOMS as a very close match to the donor kidney; this kidney can be sent to them from anywhere in Australia. This scheme covers patients who have high levels of antibodies and only 0, 1 or 2 HLA mismatches with the donor. It also allocates kidneys to patients who have a perfect HLA match with the donor, even if they have no antibodies. The exchange program also allows for kidneys to be sent from one state to another to maintain a balance between the states, so that an excess of kidneys do not move out of any one state.

About 20% (1 in 5) of all kidneys are shipped according to this Interstate Exchange program. The remaining 80% (4 in 5) kidneys are transplanted in the same state where they were donated. For local allocations the NOMS database also calculates who should receive the kidneys in each state, according to the state's allocation formula. Each State Transplant Service uses a slightly different formula to take into account differences in the number of people waiting for a transplant in that state, and other factors with the aim of ensuring similar outcome for the patients on the transplant list.

Exceptions

There are some types of kidneys that are only allocated within the state in which they are donated. This situation arises when it is particularly important to transplant the kidney quickly, or where there are technical issues, such as kidneys donated after cardiac death (DCD Donation), or kidneys donated by living patients after nephrectomy for renal pathology where the kidneys are best utilised locally. In this situation, only the state algorithm is used to allocate these kidneys.

When a suitable pancreas is donated for a simultaneous pancreas and kidney transplant, one of the donor kidneys is allocated for the recipient of the pancreas. This leaves one donor kidney available to be allocated according to the NOMS program to a kidney alone recipient. If there is a second kidney alone recipient who has a very good match at Level 1, 2 or 3 on the National Matching Score, the match to the simultaneous pancreas and kidney patient will be overridden and the second kidney will be allocated to the kidney alone patient. The patients who are matched at Level 1,

2, or 3 have a lot of antibodies in their blood that react with other people's antibodies, they therefore require a well matched kidney to ensure a successful outcome. These patients receive this allocation preference to allow the benefits of this excellent matching, as it is unlikely that another well matched kidney will become available, if at all, for a number of years.

Allocation Algorithms

The National Computer Formula that is used to determine which patients have the highest priority for an available kidney is:

Base Score	0 HLA mismatches, Peak PRA not < 50%	{Level 1}	60 000 000
Base Score	1 HLA mismatch, Peak PRA > 80%	{Level 2}	59 000 000
Base Score	2 HLA mismatches, Peak PRA > 80%	{Level 3}	58 000 000
Base Score	0 HLA mismatches, Peak PRA < 50 %	{Level 4}	57 000 000
Base Score	0 mismatches at HLA-DR, 1 mismatch at HLA-A or B, Peak PRA not > 80% and Centre Credit Difference <= -3	{Level 5}	56 000 000
Base Score	0 mismatches at HLA-DR, 2 mismatches at A or B, Peak PRA not > 80% and Centre Credit Difference <= -6	{Level 6}	55 000 000
Base score	When score is Null and Centre Credit Difference <= -20	{Level 7}	54 000 000
Paediatric bonus	if age < 18, first dialysis before 15 th birthday and on dialysis for > 1 year		+ 30 000
Recipient at same centre as Donor			+ 50 000
Centre credit balance			1000 + Patient Centre Credit
Patient Waiting Period > 0			+ Wait in months * 1
If Score is < 54 000 000, go to Relevant State Based Algorithm			
National Override List – used if not enough patients appear on the National/State allocation lists			
Base score		0	
Paediatric Bonus	if age < 18, first dialysis before 15 th birthday and on dialysis for > 1 year	+	30 000
Peak PRA > 50%		+	1000 * (peak PRA% - 50)
Patient Dialysis Waiting Period > 0		+	Wait in months * 100

New South Wales / ACT:

After the national allocation has been taken into consideration, kidney allocation within NSW from deceased donors is according to the NSW NOMS Program. This algorithm takes into account both the donor and recipient match and waiting time. With increasing time spent on dialysis, waiting time becomes more important.

National allocation currently does not occur for kidneys obtained from donation after cardiac death. Extremely marginal renal allografts on occasion may be offered as a dual allograft based on donor criteria, findings at procurement and allograft biopsy results. This only occurs once or twice a year.

The New South Wales Computer Formula that is used to determine which patients have the highest priority for an available kidney is:

State HLA		
Base Score	if no Mismatches at DR	50 000 000
	For each mismatch at A	- 1 000 000
	For each mismatch at B	- 1 000 000
Paediatric Bonus	if age < 18, first dialysis before 15 th birthday and on dialysis for > 1 year	+ 100 000
Patient Dialysis Waiting Period > 0		+ Wait in months * 100
If Score is < 48 000 000, go to State Waiting Algorithm		
State Waiting		
Base Score		40 000 000
Paediatric Bonus	if age < 18, first dialysis before 15 th birthday and on dialysis for > 1 year	+ 100 000
Patient Dialysis Waiting Period > 0		+ Wait in months * 100
Urgent Patients		
Base Score		0
Urgency bonus when urgency index > 0		+100 * urgency index (1-10)

Queensland:

The Queensland NOMS programme primarily determines who will receive kidneys by HLA matching, or by the time a patient has been on dialysis. Firstly all patients on the waiting list, who are of the correct blood, group are matched against the donor. If there are any very well matched patients (no more than 2 mismatches out of 6) then the NOMS programme allocates it to the patients with the best match. This happens about 50% of the time. The other 50% of the time, there is nobody on the waiting list who is well matched with the donor. In these cases NOMS ignores the HLA matching altogether, and produces a list of ABO blood group compatible patients, in order of who has been on dialysis longest. A patient's renal physician should be able to give the patient an approximate idea of how long it will take them to be allocated an organ for their blood group, and whether there are any special circumstances that might make it harder than usual for them to get a kidney.

The Queensland Computer Formula that is used to determine which patients have the highest priority for an available kidney is:

State HLA	
Base Score	50 000 000
For each mismatch at A	- 1 000 000
For each mismatch at B	- 1 000 000
For each mismatch at DR	- 1 000 000
Patient Dialysis Waiting Period > 0	+ Wait in months * 100
If Score is < 48 000 000, go to State Waiting	
State Waiting	
Base Score	40 000 000
Patient Dialysis Waiting Period > 0	+ Wait in months * 100
Urgent Patients	
Base Score	10 000 000
Urgency bonus when urgency index > 0	+100 * urgency index (1-10)

South Australia:

The South Australian NOMS programme determines who will receive kidneys by HLA matching and by the time a patient has been on dialysis. Firstly all patients on the waiting list, who are of the correct blood group are matched against the donor. If there are any very well matched patients (no more than 3 mismatches out of 6) then the NOMS programme allocates it to the patients with the best match. This happens about 30% of the time. The other 70% of the time, there is nobody on the waiting list who is well matched with the donor. In these cases NOMS ignores the HLA matching altogether, and produces a list of ABO blood group compatible patients, in order of who has been on dialysis longest.

The South Australian Computer Formula that is used to determine which patients have the highest priority for an available kidney is:

State HLA	
Base Score	30 000 000
For each mismatch at A	- 10 000 000
For each mismatch at B	- 10 000 000
For each mismatch at DR	- 10 000 000
If total mismatches is > 3 then reset score to zero	
Patient Dialysis Waiting Period > 0	+ Wait in months * 1
Urgent Patients ó no score set, patients listed in Urgency listing	
Base Score	0
Urgency bonus when urgency index > 0	0

Victoria / Tasmania:

If Victorian patients do not fit the criteria for national allocation, Victorian NOMS Program assigns a starting score of 40,000,000. Patients lose 20,000,000 for each HLA- B or DR mismatch. Therefore if a Victorian patient has 2 HLA-B and/or DR mismatches their score reduces to zero and any added scores are for months on dialysis. i.e. waiting time only applies. However waiting time also applies in the matching list. For example if a patient has one donor HLA-DR mismatch and has been waiting 60 months for a graft, the score will be 20,000,060.

The Victorian Computer Formula that is used to determine which patients have the highest priority for an available kidney is:

State HLA	
Base Score	40 000 000
For each mismatch at B	- 20 000 000
For each mismatch at DR	- 20 000 000
If total mismatches at B and DR is > 2 then reset score to 0	
Patient Dialysis Waiting Period > 0	+ Wait in months * 1
If score <10 000 000 and previous transplants > 0 and PRA > 20 then remove from list	
Urgent Patients ó no score set, patients listed in Urgency listing	
Base Score	0
Urgency bonus when urgency index > 0	0

Western Australia:

The National Allocation Scheme will ensure Western Australian patients, particularly those who are highly sensitised, will be offered well matched kidneys from the National pool when available. After this allocation is taken into account, the Western Australian NOMS Program allocates kidneys based on a combination of HLA matching (tissue types) and waiting time. For patients with uncommon tissue types, the WA algorithm gives considerable emphasis on waiting time ensuring that with increasing time, they will receive priority above those with a better-matched kidney.

The Western Australian Computer Formula that is used to determine which patients have the highest priority for an available kidney is:

State HLA	
Base Score	40 000 000
For each mismatch at A	- 3 000 000
For each mismatch at B	- 3 000 000
For each mismatch at DR	- 5 000 000
Patient Dialysis Waiting Period > 0	+ Wait in months * 100 000
Homozygous at HLA-DR and Waiting > 5 years	+ 5 000 000

Liver

Liver Transplantation Eligibility and Allocation Criteria

Introduction:

Liver transplantation is a highly successful therapy for patients with end-stage liver disease, small intra-hepatic hepatocellular carcinomata and/or other liver-dependent systemic diseases. Such patients, when carefully selected such that those with life-threatening medical or psychosocial co-morbidities are excluded, have extremely good post-transplant outcomes. The Australian and New Zealand Liver Transplant Registry (ANZLTR) records that more than 80% of liver transplant recipients enjoy at least 5 years of post-transplant survival.⁴⁷ Mean post-transplant survival times exceed 20 years.⁴⁷ The limiting parameter in applying liver transplantation as a therapy is not cost (the therapy is very cost-effective) but rather the availability of donor organs. The scarce nature of such organs means that clear cut eligibility and allocation guidelines are required to ensure a just and equitable system for the delivery of this therapy in Australia and New Zealand.

List of currently recognised Liver Transplant Units

New South Wales	Royal Prince Alfred Hospital
Queensland	Princess Alexandra Hospital
Victoria	The Austin Hospital
South Australia	Flinders Medical Centre
Western Australia	Sir Charles Gardiner Hospital
New Zealand	Auckland Hospital

Eligibility Criteria

Chronic liver disease with life-threatening complications

In general this means having a Model of End Stage Liver Disease (MELD) score of >15 (adult) or a Paediatric End Stage Liver Disease (PELD) score of >17 (child of <16 years) or evidence of an hepatocellular carcinoma (HCC) within the criteria set out by the University of California and San Francisco (UCSF).⁴⁸ This criteria requires that there be either a single lesion not exceeding 6.5 cm or 2-3 lesions, none exceeding 4.5 cm, with a total tumour diameter not greater than 8cm. Additional

indications include: resistant ascites; recurrent encephalopathy; recurrent bacterial peritonitis or septic hydrothorax; severe choledocholithiasis with infection; recurrent or persistent gastrointestinal hemorrhage; poor and failing nutrition; fibrolamellar variant of HCC (which may be outside UCSF criteria); neuroendocrine tumours; hepatopulmonary syndrome; portopulmonary hypertension; metabolic disorders with severe symptoms; polycystic liver disease with severe symptoms and other conditions that have a mortality rate of >50% within 2 years if liver transplantation is not offered.⁴⁹

Acute liver disease unlikely to result in spontaneous recovery

As determined by the King's College of London criteria (see Explanatory Note 1)

General outcome requirements for liver transplant candidates

In determining suitability for liver transplantation, the minimum expected post transplant survival for a group of such patients must not be less than 50% at 5 years. This minimum value could vary inversely with organ availability rates and depending on expected levels of cost-utility.

Exclusion criteria:

1. General exclusions

Patients will be excluded from listing if they have medical, surgical or psychosocial problems that, based on the best available evidence, would make a 50% chance of a 5 year post-transplant survival unlikely. Such problems include (but are not limited to): malignancy (prior or current, except for HCC within UCSF criteria, fibrolamellar variant tumors or neuroendocrine tumors); infection (other than hepatitis B, hepatitis C or human immunodeficiency virus infection); cardiovascular disease; severe metabolic syndrome (including type II diabetes, morbid obesity, hypertension, steatohepatitis, and/or sleep apnoea); previously demonstrated lack of adherence to treatment advice (including advice offered during drug or alcohol cessation programs); lack of social support; and, severe, irreversible neurocognitive impairment.

2. Exclusions after listing (delisting)

Delisting will occur when listed patients with HCC fall outside the UCSF criteria, when MELD scores fall below 15 or when co-morbidities have reached such a level that a 50% chance of 5 year post-transplant survival seems unlikely.

Special circumstances:

Hepatopulmonary syndrome

Liver disease-induced shunting as identified by oxygen desaturation and the demonstration of such shunting using non-invasive imaging (bubble echocardiography or scintigraphy). The minimum acceptable level of oxygenation in such patients ought to be a PaO₂ of >200 mmHg on 100% FiO₂.

Portopulmonary hypertension

Portal hypertension-induced pulmonary hypertension. Safe transplantation can be performed when the mean pulmonary artery pressure is <45 mmHg and when pulmonary vascular resistance is <4 Woods units (<320 dynes/sec/cm⁵). Patients should show responsiveness to one or more of the following drugs used to reduce pulmonary vascular resistance; iloprost, bosentan, sildenafil or treprostinil.

Combined liver and kidney transplantation

Patients must have a cause for their renal failure other than hepatorenal syndrome and an estimated glomerular filtration rate of <30 mls/min.

Combined liver and heart or lung transplantation

Eligibility criteria for the liver component of such a combined transplant may fall outside normal liver eligibility criteria because of issues related to the other component(s) of such a combined transplant.

Deceased Donor Liver Allocation

Any liver becoming available within Australia or NZ is first to be allocated to any patient listed according to the **urgent listing criteria** previously agreed upon by all units in both countries. The categories of urgently listed patients include:

Status 1

Patients with acute liver failure that are ventilated and in an intensive care unit

Status 2a

Patients with acute liver failure that are not yet ventilated but nevertheless meet King's College criteria (see Explanatory Note 1) or paediatric patients that are very unwell in an intensive care unit

Status 2b

Paediatric patients with severe metabolic disorders or hepatoblastoma for whom a limited time period exists during which liver transplantation is possible

If no patient is listed in the urgent category, then the local liver unit will allocate livers according to the following principles:

The liver will go to the recipient with the highest MELD or PELD score

If not allocated according to MELD/PELD scores then allocation will be based on:

- The quality of the donor liver (donor risk score)
- The presence of a paediatric recipient on the list in need of a split liver (if the donor is of suitable quality)
- If the donor is paediatric then paediatric recipients have priority for that liver
- The presence of a patient on the list with HCC on the list whose HCC MELD score (see Explanatory Note 2) is higher than any non-HCC patient's standard MELD score.
- Donor size - smaller recipients may not accommodate livers from very large donors and, conversely, large recipients may not be well-served by a very small liver.
- Logistic concerns such as cold storage time, staff mix and availability, anticipated operative time etc.
- The presence of a patient on the list who would not normally qualify for priority based on liver disease but for whom severe, correctable extra-hepatic disease mandates some priority (e.g. familial amyloidosis, oxalosis, protein C deficiency etc)
- Blood group O liver will be used for blood group O recipients except in urgent cases
- Blood group A₂ and A₂B livers will be considered for blood group O and B patients respectively when waiting times are long and provided recipient antibody levels allow the safe transplantation of such organs

All allocation decisions will be recorded for subsequent audit purposes, including exceptions.

Explanatory Notes

Explanatory Note 1

King's College Hospital Criteria for Liver Transplantation in Acute Liver Failure

1. Paracetamol (acetaminophen) induced acute liver failure:
 - (i) pH of arterial blood (after rehydration) of <7.3, or
 - (ii) All three of:
 - (a) INR >6.5
 - (b) Serum creatinine >300 micromole/l
 - (c) Grade III or IV encephalopathy
2. Non-paracetamol (acetaminophen) induced acute liver failure:

- (i) INR >6.5, or
- (ii) Three of the following 5 criteria:
 - (a) Age <11 or >40
 - (b) Serum creatinine >300 micromole/l
 - (c) Jaundice to coma time of >7days
 - (d) INR >3.5
 - (e) Drug toxicity

Explanatory Note 2

HCC MELD score

If the maximum tumour diameter is less than or equal to 2 cm there will be no HCC MELD points allocated to the patient. That patient's score will be the standard MELD score only.

If the maximum tumour diameter is greater than 2 cm but total tumour burden is within UCSF criteria (no tumour greater than 6.5 cm in diameter and total diameter of all tumours not more than 8 cm) then a score of 22 will be allocated to the patient. An additional 2 points will be allocated for every 3 months on the waiting list.

Lung

Lung Transplantation Eligibility and Allocation Criteria

Introduction

Lung transplantation is a highly effective treatment for advanced lung disease; however its use is limited by the scarcity of suitable donor organs. For this reason, lung transplantation is offered only to patients who have end-stage lung disease (life expectancy less than two years without transplantation), and who have exhausted all alternative treatment options.

Infant lung transplants (currently not available in Australia and New Zealand) and living related lung transplants have their own specific issues and are not included in these protocols.

Assessment, listing and transplantation can only occur after careful evaluation by a recognised multidisciplinary Australian or New Zealand Lung Transplant Unit. Lung transplantation is a complex therapy with significant risks, and a careful evaluation of all organ systems (with appropriate specialist advice as needed) is mandatory to evaluate a potential patient's risk of short and long-term morbidity and mortality. As there may be significant co-morbidities and contraindications, it follows that not all possible recipients will prove acceptable for transplantation.

There are recent international guidelines that were formulated with Australian input, and Australian and New Zealand units broadly follow these recommendations with local interpretation.⁵⁰

Currently Recognised Lung Transplant Units

New South Wales	St Vincent's Hospital
Queensland	Prince Charles Hospital
Victoria	The Alfred Hospital
	Royal Children's Hospital (Paediatric)
Western Australia	Royal Perth Hospital
New Zealand	Auckland City Hospital

Inclusion Criteria

1. Respiratory failure despite optimal medical, interventional and surgical treatment.
2. Poor quality-of-life, potentially with intractable symptoms and repeated hospital admissions (e.g. NYHA Class III-IV)

Exclusion Criteria

Includes but is not limited to:

1. Active malignancy- in general a 5 year disease free interval is prudent
2. Irreversible significant dysfunction of other organs or body systems ó combined organ transplant (e.g., heart/lung) may be a consideration, but patients must fit Guideline eligibility requirements for both organs and have a plausible strategy for allocation
3. Non-curable chronic infection
4. Documented non-adherence, or inability to comply with complex medical therapy or office follow-up (e.g., untreatable psychological or psychiatric condition)
5. Substance addiction (e.g., alcohol, tobacco or illicit drug use) that is either active or within the last 6 months
6. While age is not by itself an absolute exclusion criterion, it is likely that the presence of multiple co-morbidities in patients more than 65 years of age would exclude the majority of such patients from consideration.⁵¹

Donor Lung Allocation

Lung Donor Suitability Criteria

1. Acceptable General Organ Donor Criteria
2. Age 5-65 years
3. No significant untreatable lung disease (and no known significant pleural disease for DCD lung donation)
4. Arterial blood gases on 100% FiO₂ and 5cm PEEP >250mmHg (or equivalent PaO₂/FiO₂ ratio)

Required Information for Allocation

1. Accurate lung disease and treatment history [especially smoking (cigarettes and marijuana), asthma and aspiration may determine single vs bilateral lung transplant considerations]

2. Accurate height and race (used to estimate total lung capacity)
3. Weight (only used in consideration of combined heart/lung transplant)
4. Investigations
 - ABO Blood group
 - Arterial blood gases on 100% FiO₂ and 5cm PEEP
 - Chest Xray and lung field measurements within 24hrs
 - Fibreoptic bronchoscopy (if possible)
 - Donor/recipient lymphocytotoxic cross-match
 - Donor/recipient CMV serology
 - Donor/recipient EBV serology (if available)

Organ Allocation and Distribution

The recognised Lung Transplant Unit in the state of the donor's hospital is offered the donation as detailed below. They have 20 minutes to respond to the offer.

State of donor hospital	Lung Transplant Unit
New South Wales/ACT	New South Wales
Queensland	Queensland
Victoria/Tasmania	Victoria
Western Australia	Western Australia
South Australia/Northern Territory	On rotation through above states

If the home state declines the offer, then the lung donation offer is made on to the non-home state recognised Lung Transplant Units, with a 20 minute response time. The non-home state offer is based upon a rotation kept by each state donor co-ordination team, such that the first non-home state offer is rotated through each transplanting state in strict turn. If the first non-home state declines the offer, the next is asked until all units have been asked.

If all recognised lung transplant units refuse the offer it is then rotated through any units that have non-nationals awaiting transplantation.

The acceptance of lungs by a unit depends on a large variety of technical and logistic factors, including the availability of a suitable potential recipient (see below).

Individual Patient Allocation

The allocation of donor lungs is complicated by the considerable issues of logistics and the permutations/combinations of the different options of potential lung (and or

heart) transplant that a cardiothoracic transplant unit need to consider when donor organs are offered. Donor lungs will be allocated considering the following criteria:

1. ABO compatibility
2. Size compatibility
3. The absence of a positive T cell crossmatch

Where more than one potential recipient meets the above criteria the first choice will be determined by the following process:

4. Clinical urgency*
Logistics**
Long-term outcome benefit***
5. Recipient waiting time, all other factors being equal

Explanatory Notes

* **Clinical urgency:** Graded by level of support required and evidence of rapidity of deterioration of underlying indication for transplant.

▪ **Level of support** includes, but not limited to the following

- ECMO
- Invasive mechanical ventilation
- Non-invasive ventilation
- High-flow O₂ requirement
- Low-flow O₂ requirement
- Prolonged or recurrent hospitalisation
- Other support devices such as continuous IV therapies

▪ **Rapidity of deterioration** includes, but not limited to the following

- change in NYHA functional Class or MRC grade
- significant fall in lung function parameters
- significant fall in PaO₂
- significant rise in PaCO₂
- significant fall in 6 Minute Walk Test distance
- need for escalation in level of support as above
- time course of progression of radiological changes
- development of symptomatic pulmonary hypertension
- development of refractory right heart failure

**** Logistics includes**

- Time of retrieval and operation room availability
- Location of recipients and/or donor: (local, interstate, international)
- Type (ie. road or air) and availability of transport to bring recipient to the transplant centre, and to take retrieval team to donor hospital
- Availability of required team members for the retrieval, lung transplant(s) and related cardiac transplants (paired donor heart or domino heart transplant)
- Experience of team members
- Availability of ICU beds
- Operation type (lobar, single, bilateral, heart/lung)
- Availability of crossmatching
- Concerns regarding donor instability
- Donor family wishes regarding timing

***** Long-term outcome benefit includes**

- Comorbidities such as osteoporosis, gastroesophageal reflux, known coronary or peripheral vascular disease, carriage of panresistant organisms, poor rehabilitation potential, history of malignancy, advanced age, lack of compliance, morbid obesity or malnutrition and other relative contraindications for lung transplantation which have been shown to be associated with an inferior outcome benefit.

Pancreas & Islet

Pancreas and Islet Transplantation Eligibility and Allocation Criteria

Introduction

Pancreas Transplantation is undertaken by the two National Programs in Australia and the single National New Zealand Program. The majority of solid organ transplants are undertaken as simultaneous pancreas and kidney transplants.⁵² A small minority of transplants are undertaken as pancreas transplants alone either after a kidney transplant or in patients with good renal function not requiring a kidney transplant. There are very small numbers of patients with exceptional circumstances for whom pancreas alone transplantation is deemed appropriate.

Islet transplantation is currently performed under a Research Program funded partly by the NHMRC and partly by the Juvenile Diabetes Foundation International. The trial is monitored under the provisions of the TGA Clinical Trials Notification scheme.

Currently Recognised Simultaneous Pancreas and Kidney Transplant Units

A Simultaneous Pancreas and Kidney transplant unit is defined as a clinical service of a State Public Hospital that actually performs the relevant transplant procedure. The following units are state approved transplant programs.

New South Wales	Australian National Pancreas Transplant Unit Westmead
Victoria	Australian National Pancreas Transplant Unit Monash
New Zealand	New Zealand National Pancreas Transplant Unit Auckland

Currently Recognised Clinical Islet Separation Facilities

A clinical islet separation facility is defined as a clinical facility of a State Public Hospital that actually separates islets from human pancreata under an HREC approved protocol and has the required regulatory approval/licensing

NSW Westmead Islet Laboratory	(HREC Approved protocol)
VIC St Vincent's Islet Laboratory	(HREC Approved protocol)

Currently Recognised Clinical Islet Transplant Programs

A Clinical Islet Transplant unit is defined as a clinical service of a State Public Hospital that actually performs the relevant transplant procedure under HREC approved protocols.

NSW Westmead Hospital	(HREC Approved protocol)
VIC St Vincent's Hospital	(HREC Approved protocol)
SA The Queen Elizabeth Hospital	(HREC Approved protocol)

Currently Recognised Research Islet Separation Facilities

A research Islet facility is defined as a State Public Hospital or Research Institute that actually separates islets from human pancreata for research under an HREC approved protocol with whatever regulatory approval/licensing is required.

NSW Westmead Islet Laboratory	(HREC Approved protocol)
SA The Queen Elizabeth Hospital/IMVS	(HREC Approved protocol)
VIC St Vincent's Islet Laboratory	(HREC Approved protocol)

Inclusion Criteria

Simultaneous Pancreas and Kidney Transplantation Referral Criteria

Patients must be referred to a pancreas transplant unit by their caring nephrologist and/or endocrinologist. Patients will be reviewed by a pancreas transplant unit if they meet the following criteria:

1. Type I diabetes with Insulin dependence
2. Age < 50 years
3. GFR < 30 ml/min
4. Absence of significant cardiac disease or adequately treated cardiac disease
5. BMI < 35
6. Patent Iliac Vessels

Simultaneous Pancreas and Kidney Transplantation Listing Criteria

Patients may be referred and assessed if they meet the above criteria but they will not be listed for transplantation until they meet the following criteria:

1. Insulin dependence reversible by Pancreas Transplantation
2. Age < 50 years at listing
3. GFR < 15 ml/min and Dialysis impending
4. Non-smoker or cessation of smoking for more than 3 months
5. BMI < 30, (BMI 30-35 is a relative contraindication)

Exclusion Criteria

Simultaneous Pancreas and Kidney Transplantation Exclusion Criteria for Referral

1. Significant cardiac disease or inadequately treated cardiac disease

Simultaneous Pancreas and Kidney Transplantation Exclusion Criteria for Listing

1. Significant cardiac disease or inadequately treated cardiac disease
2. Significant Vascular disease
3. Continuous anti-platelet therapy
4. Significant Psychiatric disease
5. Demonstrated non-compliance with medical therapy
6. Addiction to non-prescription drugs

Islet

Patients will be entered onto the National Islet transplant list by recognized Clinical Islet Transplant Programs. Patients on the National Islet transplant list will be associated to a recognized Clinical Islet Separation Laboratory, by the Clinical Islet Transplant Program Each Clinical Islet Transplant Program for each Recipient Blood Group type may enter a maximum of two unsensitized and one sensitized patient (PRA >10%) onto the active list at any one time

Inclusion Criteria

Islet

1. Type 1 Diabetes for 5 yrs. or more
2. Age 18-65
3. Severe hypoglycaemic unawareness (documented BSL < 3mmol/l without awareness) that has not responded to optimal conventional insulin therapy, as assessed by an endocrinologist.
4. Creatinine clearance > 75/ml/min/1.73m²
5. Serum Creatinine < 130 µmol/l
6. 24 hr Urine Protein estimation < 300mg/day
7. Weight < 75 Kg
8. The patient has read and signed the Informed Consent Form.
9. Absence of donor reactive antibodies by Luminex and cytotoxic crossmatch
10. Willingness to use effective contraception measures
11. Ability to understand the trial protocol and informed consent

Exclusion Criteria

Islet

1. Patients with weight > 75 kg
2. C-peptide response to arginine (5 gm I.V.) Exclude any C-peptide greater or equal to 0.3 ng/mL at 2, 3, 4, 5, 7, and 10 min post infusion.
3. Creatine clearance < 75 mL/min/1.73 m²
4. Serum creatinine > 130 µmol/l
5. 24 hr Urine Protein estimation >300 mg/day
6. Baseline Hb < 12 gm/dL in women, or < 13 gm/dL in men
7. Baseline LFT's outside of normal range
8. Insulin requirement > 0.7 IU/kg/day
9. HbA1c > 12%
10. Serum Cholesterol > 10 mmol/l
11. Systemic Corticosteroid usage
12. Treatment with terfenadine, cisapride, astemizole, pimozone, or ketoconazole (that is not discontinued prior to sirolimus administration).
13. A positive pregnancy test or desire to fall pregnant within the timeframe of the trial.
14. Malignant disease other than localized and excised skin Squamous Cell or Basal Cell Carcinoma
15. Hepatic disease, including any form of active viral hepatitis, portal venous abnormality or cirrhosis
16. Chronic Pancreatitis
17. Significant cardiac disease including ischaemic and valvular heart disease
18. Respiratory disease including clinically significant asthma, bronchiectasis or obstructive airways disease.

Donor Pancreas Allocation:

Standard Criteria

1. General Organ Donor Criteria must be met
2. No known diabetes mellitus or insulin dependence
3. No known pancreatic trauma - may be considered for separated islets
4. No history of alcoholism or chronic pancreatitis
5. Donor age under 45 years.

Extended Criteria – Donation After Cardiac Death

1. General Organ Donor Criteria for Donation after Cardiac Death must be met
2. No known diabetes mellitus or insulin dependence

3. No known pancreatic trauma - may be considered for separated islets
4. No history of alcoholism or chronic pancreatitis
5. Donor age under 35 years.
6. Maximum ischaemia time from withdrawal of treatment to organ perfusion
7. Liver deemed suitable for transplantation.

Required Information for Allocation

Pancreas

1. Blood group
2. Body weight
3. Approximate height
4. Laboratory tests: -
 - General Organ Donor Criteria for viral studies
 - HIV, Hep BsAg, Hep C, CMV
 - electrolytes, glucose, amylase and or lipase
 - current use of Insulin, dextrose and steroids

Islet

1. Blood group
2. Body weight
3. Approximate height
4. Laboratory tests: -
 - General Organ Donor Criteria for viral studies
 - electrolytes, glucose, amylase
 - HIV, Hep BsAg, Hep C, CMV
 - current use of Insulin, dextrose and steroids

Organ Retrieval Mechanisms

The unit accepting the pancreas offer is responsible for arranging the surgical procedure using a team of qualified surgeon(s) and associated staff. The unit accepting the pancreas offer is responsible for liaison with the relevant donor co-ordinator to achieve surgical starting times mutually acceptable to the donor hospital and all donor surgical teams involved. The unit accepting the pancreas offer is responsible for ensuring that the pancreas meets medical standards for organ donation and is delivered in a safe and appropriate manner to the recipient unit's hospital.

Organ Allocation and Distribution

There is no urgent classification for pancreas or islet recipients.

Simultaneous Pancreas and Kidney

ABO compatibility: absolute requirement
Lymphocytotoxic crossmatch: peak and current serum negative test required
HLA matching: not required for allocation
Size and weight compatibility: considered at extremes of donor and recipient size
Patients are transplanted in order of referral for assessment within each blood group, within each transplanting unit

The decision about each individual offer and transplant list management are the responsibility of each recognised pancreas transplant unit.

Pancreas Alone

ABO compatibility: absolute requirement
Lymphocytotoxic crossmatch: peak and current serum negative test required
HLA matching: not required for allocation
Size and weight compatibility: considered at extremes of donor and recipient size
Patients are transplanted in order of presentation to the national pancreas transplant list within each blood group

Final acceptance of each individual offer and transplant list management are the responsibility of each recognised pancreas transplant unit.

Individual Islet Allocation

Each Islet Transplantation Program will allocate Islets to the patient waiting the longest period on the transplant list that is suitable for the islet preparation available for transplantation.

Exceptions

When a suitable pancreas is donated for a simultaneous pancreas and kidney transplant, one of the donor kidneys is allocated for the recipient of the pancreas. This leaves one donor kidney available to be allocated according to the NOMS computer program to a kidney alone recipient. If there is a second kidney alone recipient who has a very good match at Level 1, 2 or 3 on the National Matching Score the match to the simultaneous pancreas and kidney patient will be overridden and the second kidney will be allocated to the kidney alone patient. As the patients who are matched at Level 1, 2, or 3 have a lot of antibodies in their blood that react with other people's antibodies they therefore require a well matched kidney to ensure a successful outcome. These patients receive this allocation preference to allow the benefits of this excellent matching, as it is unlikely that another well matched kidney will become available, if at all, for a number of years

Appendix 1

Membership and Terms of Reference

Standing Committees of TSANZ – Terms of Reference

It is expected by TSANZ that its Standing Committees represent the interests and views of their transplantation group in Australia and New Zealand. Although there is some variation in the constituency and mode of operation of the individual groups, the areas listed below are a set of minimum requirements of each Standing Committee.

Each Standing Committee acts as the peak body for the organ group it represents. As such it is critical that the Committee is truly representative of the individuals, units and States taking part in the given transplant area and able to provide standards and policies that will be adopted nationally.

The chair of each Standing Committee will report to the TSANZ Council via the chair of the Standing Committees on Council on a regular basis. The chairs of individual Standing Committees will meet by teleconference around June of each year with a face to face meeting in October of each year. Additional meetings may be required for special circumstances or agenda items.

It is expected that each Standing Committee:

- Will act as the peak body for their special interest group in areas of retrieval, allocation and standards of practice.
- Will formulate standards of practice which are audited and reviewed regularly.
- Will oversee and regularly review allocation algorithms for their organ group.
- Will provide forum for discussion of new or emerging therapies or practices in their field of transplantation.
- Will have auditable and transparent processes and operation.
- Will regularly review information they make available on TSANZ website for accuracy and current applicability.
- Will have a wide representation of its constituency enabling effective consultation with the interest group community at large. Members of the Standing Committee and their chair will undertake to report back to the general membership.
- Will have consumer representation as required of any peak body.
- Will be responsible to TSANZ Council to advise on views and interests of their group at large and will therefore establish communication forums to ensure this occurs effectively.

- Will have documented process of election to the membership of the Standing Committee, their chair and terms of appointment. The reporting processes to the constituency will also be documented.

It is expected therefore that any change to practice or standards can be dealt with by these Committees rather than requiring external bodies to regulate transplantation practices.

*Working Party – TSANZ Combined Standing Committee Meeting
March 2009*

Name	State	Name	State
Holly Northam	ACT	Jonathan Fawcett	QLD
Richard McClusky	ACT	Sharon Cull	QLD
Carrie Alvaro	NSW	Kathy Hee	SA
Emily Beck	NSW	James Dellit	SA
David Joseph	NSW	Mark Brook-Smith	SA
Yves Kerdraon	NSW	John Chen	SA
John Males	NSW	Steven Nailer	SA
Kellie Thomas	NSW	Christine Russell	SA
Alison Bond	NSW	Michael Fink	VIC
Leigh McKay	NSW	Marisa Herson	VIC
Jenni Wright	NSW	Ian Michell	VIC
Trish Wills	NSW	Justin Negri	VIC
Richard Allen	NSW	Allan Turner	VIC
Josette Eris	NSW	Peter Bergin	VIC
Geoff McCaughan	NSW	Anne Griffiths	VIC
Deborah Verran	NSW	Bron Levvey	VIC
Allan Glanville	NSW	Greg Snell	VIC
Michelle Harkess	NSW	Glen Westall	VIC
Paul Jansz	NSW	Rhonda Holdsworth	VIC
Peter Macdonald	NSW	Violet Marion	VIC
Fiona Mackie	NSW	Frank Ierino	VIC
Jeremy Chapman	NSW	Robert Jones	VIC
Henry Pleass	NSW	John Kanellis	VIC
Paul Robertson	NSW	Alan Saunder	VIC
Lee Wood	NT	Rob Weintraub	VIC
Janice Langlands	NZ	Winita Hardikar	VIC
Peter Ruygrok	NZ	Anne Cowie	WA
Ed Gane	NZ	Bulang He	WA
Tanya McWilliams	NZ	Linda Manning	WA
Steve Munn	NZ	Melissa Smith	WA
Helen Evans	NZ	Frank Christiansen	WA
Tina Coco	QLD	Lawrence Dembo	WA
Anthony Griffin	QLD	Ashley Irish	WA
George Javorsky	QLD	Gary Jeffrey	WA
Glenda Balderson	QLD		
Scott Campbell	QLD		

Appendix 2

Process Report

Background

The Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA) was established on the 1st of January 2009 with the aim of creating a nationally consistent and coordinated approach to organ and tissue donation and transplantation.² Prior to the creation of the AOTDTA, the allocation of organs for transplantation was guided by state-specific guidelines, local hospital protocols and procedures and protocols developed by TSANZ and the Australian Transplant Coordinators Association (ATCA), which may have resulted in some variance between tissue transplant centres and across state and territory jurisdictions.

On the 16th of January 2009, as part of the Australian Government's reform package for organ and tissue donation for transplantation, TSANZ obtained funding from the Australian Department of Health and Aging (subsequently transferred to the AOTDTA) to enhance the role of its clinical standing committees, allowing the committees to meet more regularly, and integrate the existing organ allocation processes into one agreed protocol. The TSANZ clinical standing committees comprise a multidisciplinary group of clinicians, health-care professionals and consumer representatives. As part of this funding, two project staff have been employed to support the development of the revised protocol.

TSANZ Clinical Standing Committees

The TSANZ clinical standing committees convened for a two-day meeting on the 19th and 20th of March 2009 to revise the existing eligibility and allocation criteria for organ transplantation. Subsequent meetings were held between the 16th and 19th June 2009 for further review of the revised criteria. The criteria for this revised protocol are supported by the best-available scientific evidence, however as this is a protocol rather than a guideline, a systematic review of the evidence is not required.

Purpose and Scope

The purpose of developing nationally uniform eligibility and allocation criteria for organ transplantation is to support consistency in clinical practice. This will ensure that the management of transplant lists and the allocation of organs is effective, equitable and transparent, regardless of where the donor and recipient reside.²

This protocol is intended for clinicians and health care professionals involved in the care of patients with end-stage organ disease who may benefit from organ transplantation. This protocol also provides transparent and evidence-based

information to patients in need of organ transplantation, and the community interested in the allocation of donated organs for transplantation.

Public consultation

The process for public consultation involves invitation for comment via an advertisement in the Weekend Australian on the 8th August 2009. This advertisement will include a link to the draft protocol on the TSANZ website with clear processes available for provision of comments. Comment will also be invited via targeted mailing to key industry groups for the opportunity to provide written feedback. All feedback will be reviewed by the TSANZ clinical standing committees, and where required, changes to the draft protocol will be implemented.

Dissemination and implementation

A plan for the dissemination and implementation will be outlined in the final protocol. It is anticipated that the final protocol will be available from the TSANZ website.

Scheduled review

It is intended that the TSANZ clinical standing committees will meet annually to review the final protocol. Where required, the protocol will be revised if evidence emerges that supports improvements in clinical practice and outcomes. As the National Reform Agenda has targeted funding aimed at increasing deceased organ donations in Australia, an increase in the number of organs available will both decrease the time from listing until transplantation and may result in a revision of the criteria for listing and allocation protocols in light of the potential increase in the number of organs available for transplant.

Appendix 3

Abbreviations & Acronyms

ACT:	Australian Capital Territory
ANZLTR:	Australian and New Zealand Liver Transplant Registry
AOTDTA:	Australian Organ and Tissue Donation and Transplantation Authority
ATCA:	Australasian Transplant Co-ordinators Association
DCD:	Donation after Cardiac Death
HREC:	Human Research Ethics Committee
ICU:	Intensive Care Unit
NHMRC:	National Health and Medical Research Council
NOMS:	National Organ Matching System
NSW:	New South Wales
NT:	Northern Territory
QLD:	Queensland
RTAC:	Renal Transplant Advisory Committee
SA:	South Australia
TAS:	Tasmania
TGA	Therapeutic Goods Administration
TSANZ:	Transplantation Society of Australia and New Zealand
UCSF:	University of California and San Francisco
VIC:	Victoria
WA:	Western Australia

Appendix 4

Definitions

ABO:

A classification system for human blood that identifies four major blood types based on the presence or absence of two antigens, A and B, on red blood cells. The four blood types (A, B, AB, and O, in which O designates blood that lacks both antigens) are important in determining the compatibility of blood for transfusion.

Automatic Implanted Cardioverter Defibrillator (AICD):

A surgically implanted device that automatically detects and corrects potentially fatal arrhythmias.

Biventricular Assistive Device (BVAD):

A ventricular assist device that helps both ventricles of the heart. It helps the right ventricle of the heart to pump blood to the lungs and the left ventricle to pump blood to the body

Body Mass Index (BMI):

Body mass index (BMI) is used to estimate total amount of body fat. It is calculated by dividing weight in kilograms by height in metres squared (m²).

Cytomegalovirus (CMV):

Any of a group of herpes viruses that enlarge epithelial cells and can cause birth defects; can affect humans with impaired immunological systems, such as transplantation recipients.

Electrocardiogram (ECG):

A graphic tracing of the variations in electrical potential caused by the excitation of the heart muscle and detected at the body surface. The normal electrocardiogram is a scalar representation that shows deflections resulting from cardiac activity as changes in the magnitude of voltage and polarity over time and comprises the P wave, QRS complex, and T and U waves.

Extracorporeal Membrane Oxygenator (ECMO):

A device that oxygenates blood outside the body and returns the blood to the circulatory system. The technique may be used to support an impaired respiratory system.

Glomerular Filtration Rate (GFR):

A kidney function test in which results are determined from the amount of ultrafiltrate formed by plasma flowing through the glomeruli of the kidney. The amount is calculated from inulin and creatinine clearance, serum creatinine, and blood urea nitrogen.

Hepatitis B (HepB):

An infection of the liver that is caused by a DNA virus, is transmitted by contaminated blood or blood derivatives in transfusions, by sexual contact with an infected person, or by the use of contaminated needles and instruments. The disease has a long incubation and symptoms

that may become severe or chronic, causing serious damage to the liver. Also called *serum hepatitis*.

Hepatitis B Surface Antigen (HepBsAg):

A serologic marker on the surface of HBV. It can be detected in high levels in serum during acute or chronic hepatitis.

Antibody to Hepatitis B core Antigen (HepBcAb):

Is an antibody to the hepatitis B core Antigen. The core antigen is found on virus particles but disappears early in the course of infection. This antibody is produced during and after an acute HBV infection and is usually found in chronic Hepatitis B carriers as well as those who have cleared the virus, and usually persists for life.

Hepatitis C (HepC):

Hepatitis C is a form of liver inflammation that causes primarily a long-lasting (chronic) disease. Acute (newly developed) hepatitis C is rarely observed as the early disease is generally quite mild. Spread mainly by contact with infected blood, the hepatitis C virus (HCV) causes most cases of viral liver infection not due to the A and B hepatitis viruses.

Human Leucocyte Antigen (HLA)

A group of protein molecules located on bone marrow cells that can provoke an immune response. A donor's and a recipient's HLA types should match as closely as possible to prevent the recipient's immune system from attacking the donor's marrow as a foreign material that does not belong in the body.

Human Immunodeficiency Virus (HIV):

One of two retrovirus strains, HIV-1, or HIV-2, that attacks the T-cells of the immune system with debilitating effects, producing a syndrome called Acquired Immune Deficiency (AIDS).

Left Ventricular Ejection Fraction (LVEF):

A measure of the heart's ability to pump blood.

Left Ventricle Assist Device (LVAD):

A device used to aid the pumping action of a weakened heart ventricle.

Left Ventricular Hypertrophy (LVH):

Thickening of the heart's lower left chamber. LVH is often caused by high blood pressure, valvular disease, or coronary artery disease.

New York Heart Association (NYHA) Classification:

NYHA Class I: No symptoms and no limitation in ordinary physical activity. e.g., Shortness of breath when walking, stair climbing etc.

NYHA Class II: Mild symptoms (mild shortness of breath and/or angina pain) and slight limitation during ordinary activity.

NYHA Class III: Marked limitation in activity due to symptoms, even during less-than-ordinary activity (e.g., walking short distances >20m to 100m)

NYHA Class IV: Severe limitations. Experiences symptoms even while at rest, mostly bedbound patients.

PaCO₂:

Partial pressure of carbon dioxide in the blood. Critical in regulating breathing levels and maintaining body pH.

PaO₂:

Partial pressure of oxygen in the blood.

Plasma Renin Assay (PRA):

A blood test that measures the rate of generation of angiotensin. The most commonly used renin assay, it is a screening procedure for detecting essential, renal, or renovascular hypertension, and it is also performed to diagnose and separate primary from secondary hyperaldosteronism.

Pulmonary Vascular Resistance (PVR):

The resistance offered by the vasculature of the lungs.

Appendix 5

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