THE TRANSPLANTATION SOCIETY OF AUSTRALIA AND NEW ZEALAND

ORGAN TRANSPLANTATION FROM DECEASED DONORS:

ELIGIBILITY GUIDELINES AND ALLOCATION PROTOCOLS

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Contents

List of tables

Abbreviations and acronyms

Ab	antibody
ACT	Australian Capital Territory
AICD	automatic implanted cardioverter defibrillator
ATCA	Australian Transplant Coordinators Association
BMI	body mass index
BSL	blood sugar level
CMV	cytomegalovirus
CRT	cardiac resynchronisation therapy
DBD	donation after brain death
DCD	donation after cardiac death

EBV	Epstein Barr virus
ECG	electrocardiogram
ECMO	extracorporeal membrane oxygenator
FiO_2	fractional inspired oxygen
GFR	glomerular filtration rate
HAART	highly active antiretroviral therapy
Hb	haemoglobin
HbA_{1c}	glycated haemoglobin
HBcAb	hepatitis B core antibody
HBsAb	hepatitis B surface antibody
HBsAg	hepatitis B surface antigen
HCC	hepatocellular carcinoma
HIV	human immunodeficiency virus
HLTx	heart-lung transplant
HREC	Human Research Ethics Committee
HTLV	human T-lymphotrophic virus
ICU	intensive care unit
IgG	immunoglobulin G
LFT	lung function test
LVEF	left ventricular ejection fraction
MELD	Model for End-Stage Liver Disease
MRSA	methicillin-resistant staph aureus
NHMRC	National Health and Medical Research Council
NOMS	National Organ Matching System
NSW	New South Wales
NT	Northern Territory
NYHA	New York Heart Association
O_2	oxygen
$PaCO_2$	partial pressure of carbon dioxide in the blood
PaO_2	partial pressure of oxygen in the blood
PCR	polymerase chain reaction
PEEP	positive end-expiratory pressure
PELD	paediatric end-stage liver disease
PRA	plasma renin assay
PVR	pulmonary vascular resistance
QLD	Queensland
RNA	ribonucleic acid
RTAC	Renal Transplant Advisory Committee
SA	South Australia
TAH	total artificial heart
TAS	Tasmania
TGA	Therapeutic Goods Administration
TPG	transpulmonary gradient
TPN	total parenteral nutrition
TSANZ	Transplantation Society of Australia and New Zealand
UCSF	University of California San Francisco
VAD	ventricular assist device
VIC	Victoria
VRE	vancomycin-resistant enterococcus
WA	Western Australia

Glossary of key terms

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

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).

Cardiac resynchronisation therapy (sometimes called biventricular pacing): A new form of therapy for congestive heart failure caused by dilated cardiomyopathy that uses a specialised pacemaker to re-coordinate the action of the right and left ventricles by pacing both ventricles simultaneously.

Cytomegalovirus: 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.

Epstein Barr virus (also called human herpes virus 4 [HHV-4]): A virus of the herpes family known to cause infectious mononucleosis and implicated in the causation of Burkitt's lymphoma and nasopharyngeal carcinoma.

Electrocardiogram: 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: 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: 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: An infection of the liver that is caused by a deoxyribonucleic acid (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: A serologic marker on the surface of hepatitis B virus. It can be detected in high levels in serum during acute or chronic hepatitis.

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

Hepatitis C: 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 causes most cases of viral liver infection not due to the A and B hepatitis viruses.

Human leuckocyte antigen: HLA molecules are located on most of the body's cells. They are therefore present on the cells in donated organs (be it heart, liver, kidney, lung or pancreas). These molecules allow our immune systems to recognise organs as 'foreign' or 'non-self', and this forms the basis for organ rejection. The closer the match between a donor and a recipient, the less the risk of this rejection.

Human immunodeficiency virus: One of two retrovirus strains, HIV-1, or HIV-2, that attacks the T-cells of the immune system with debilitating effects, producing acquired immune deficiency syndrome (AIDS).

Left ventricular ejection fraction: A measure of the heart's ability to pump blood.

New York Heart Association Classification:

- *NYHA Class I:* No symptoms and no limitation in ordinary physical activity (eg 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 (eg walking short distances >20m to 100m).
- *NYHA Class IV:* Severe limitations. Experiences symptoms even while at rest, mostly bedbound patients.

$PaCO_2$: Partial pressure of carbon dioxide in the blood. Critical in regulating breathing levels and maintaining body pH.

Plasma renin assay: 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: The resistance offered` by the vasculature of the lungs.

Transpulmonary gradient: The difference between the mean pulmonary artery pressure and the pulmonary capillary wedge pressure.

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

Introduction

Organ transplantation (heart, lung, liver, pancreas and kidney) is a highly effective treatment for advanced organ disease. Australia's organ transplantation success rates are some of the highest in the world, with one-year survival rates for most organs above 80%.[1]

Organ transplantation relies on the donation of organs from living or deceased donors — the focus of this document is on donation from deceased donors. The donation of organs 'is an act of altruism and human solidarity that potentially benefits those in medical need and society as a whole'.[2] Currently, the number of patients who may benefit from transplantation is far greater than the number of organs donated, and the availability of donor organs is the limiting factor in applying organ transplantation as a therapy. For this reason, organ transplantation is offered primarily to patients who have end-stage organ disease, who have exhausted all alternative treatment options and who have a reasonable prospect of returning to an active lifestyle after transplantation.

For many years, the Transplantation Society of Australia and New Zealand (TSANZ) has developed eligibility criteria for patients to be listed for organ transplantation and protocols for the allocation of organs to patients once listed. As part of the implementation of the National Reform Agenda for Organ and Tissue Donation and its key initiative of ensuring *safe, equitable and transparent national transplantation processes*, TSANZ received funding to:

- develop nationally uniform eligibility criteria to ensure there are equitable and transparent criteria for listing patients for organ transplantation; and
- develop nationally uniform allocation protocols to ensure consistency across Australia in the criteria by which donated organs and tissues are allocated.

This document was developed by TSANZ Clinical Standing Committees (see Appendices A and B), based on revision and updating of previous eligibility and allocation criteria, and has undergone comprehensive consultation through a written community consultation and feedback process, and a targeted consultation forum (see Appendix C).

Central to the eligibility guidelines and allocation protocols in this document are the following ethical principles, which are 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*.[2]

- 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.
- Decisions regarding eligibility and allocation 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).
- Decisions regarding eligibility and allocation should take into account the following ethically relevant factors:
  - relative urgency of need
  - medical factors which affect likelihood of success (eg tissue matching)
  - relative severity of illness and disability
  - relative length of time on the waiting list
  - likelihood that the recipient will (be able to) comply with the necessary ongoing treatment after transplantation.

To be eligible to be listed for organ transplantation, patients must be referred for assessment and meet the eligibility criteria outlined in the guidelines in Part A. The assessment process requires referred

1 Excell L, Hee K, Russ G (eds) (2009) *ANZOD Registry Report 2009*. Australia and New Zealand Organ Donation Registry. Adelaide, South Australia.

2 National Health and Medical Research Council (2007) *Organ and Tissue Donation After Death for Transplantation: Guidelines for Ethical Practice for Health Professionals*. http://www.nhmrc.gov.au/publications/synopses/_files/e75.pdf.

patients to be evaluated by a transplant unit; during this process the evaluation takes into consideration patients' medical history and other relevant factors to ensure that they are suitable for transplantation. After being listed, patients are regularly reviewed to ensure that they remain eligible.

Australia is a world leader in clinical outcomes for transplant patients.[3] The allocation processes outlined in the protocol in Part B vary according to the organ that is to be transplanted. Allocation of hearts, lungs and livers involves transplant 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. Patients who require kidney or pancreas transplantation are generally stable over a prolonged period of time and the allocation of these organs is based primarily on the closeness of tissue matching and the time spent on dialysis or on the transplant waiting list.

The criteria used to establish which patients are placed on the transplant list and how the organs are allocated do not determine how many patients will receive donor organs, but only which patients will be fortunate enough to receive the available donor organs. The process outlined in this document seeks to find an appropriate balance between the needs of individuals with end-stage organ failure to receive a transplant, and the need to maximise the benefit obtained from this scarce and limited public resource. It is recognised that whatever process is used, there will be many patients who would benefit from a transplant but are not able to receive one because of the limited supply of organs.

[3] Australian Government. *A World's Best Practice Reform Package for Organ and Tissue Donation for Transplantation.* Department of Health and Ageing, edCanberra. http://www.health.gov.au/internet/main/publishing.nsf/Content/B5AC5303C8932F30CA25747A000BF6A4/$File/ORGAN%20FACT%20SHEET.pdf. Accessed 30 July 2009. 2008.

Part A — Eligibility guidelines

1 ISSUES AFFECTING ELIGIBILITY

The scarcity of donor organs means that clear-cut eligibility guidelines are required to ensure a just and equitable system for the delivery of this therapy in Australia and New Zealand.

Determining eligibility in an environment where demand outweighs supply involves balancing ethical issues of equity and utility. In order to support equity, there should be no discrimination between potential recipients on the basis of anything other than established eligibility criteria as outlined in Chapters 2 to 6. However, in practical terms the allocation of organs is a complex process that depends on a range of factors besides medical need and capacity to benefit. Potential recipients may wait variable periods of time on waiting lists, regardless of their suitability or need.

Assessment for eligibility

Patients are referred to transplant units by their specialist physicians, for assessment of eligibility for transplantation. There are generally organ-specific criteria that determine whether a referred patient will go on to be assessed for eligibility for transplantation. In the case of heart and kidney disease, referred patients include those 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 the 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 organ transplantation. The transplant unit should regularly review listed patients to ensure that they remain suitable for transplantation. Listed patients 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 document.

Recognised transplant units in Australia and New Zealand are listed in Appendix E.

General inclusion and exclusion criteria

While there are specific inclusion and exclusion criteria for each organ, there are general conditions that apply across the organ types:

- *Age:* With the increasing success of transplant surgery, the age range considered suitable for transplantation has steadily widened. Although for most organs, age is not by itself an exclusion criterion, the presence of multiple comorbidities in patients over 65–70 years of age would be expected to exclude the majority of such patients from consideration.[1,2]
- *Comorbidities:* Exclusion criteria are likely to include conditions or combinations of conditions that result in an unacceptably high mortality or morbidity risk from transplantation (eg active malignancy, infection).
- *Lifestyle:* Ongoing substance abuse, including excessive alcohol consumption, cigarette smoking and illicit drug taking, are generally considered contraindications to transplantation, as is an inability to comply with complex medical therapy (eg chronic cognitive or neuropsychiatric deficits in the absence of a carer capable of taking on this role). These lifestyle factors can result in poorer outcomes.[3–9]

Organ-specific inclusion and exclusion criteria are given in Chapters 2 to 6.

All patients assessed for suitability for a transplant have the right to know whether or not they are placed on the transplant waiting list, and the reasons why they are not listed if they are evaluated as unsuitable.

International patients

TSANZ endorses the Declaration of Istanbul on organ trafficking and transplant tourism.[10,11] In view of the existing gap between donor organ supply and demand, TSANZ considers it inappropriate for international patients (non-Australian and non-New Zealand citizens or permanent residents) to be assessed for possible transplantation, except under exceptional circumstances. An example of this might be when an international visitor develops acute organ failure that would normally warrant

consideration for transplantation and is too unwell to return to their home country — in this situation it needs to be established that the visitor will return to an environment that permits appropriate ongoing post-transplant surveillance and treatment.

2 HEART RECIPIENT SUITABILITY CRITERIA

Heart transplantation is a highly effective treatment for patients with advanced heart disease. Heart transplant recipients in Australia or New Zealand survive on average 14 years after transplantation with one-third of patients surviving more than 20 years.[1] This compares with an average survival of less than 2 years for eligible patients who are unable to undergo transplantation.[2]

Recent Australian data show that in 2006, approximately 263,000 Australians experienced chronic heart failure, of whom 2,350 died from end-stage heart disease.[3] In the same year it was estimated that heart failure was the major contributor to the deaths of another 15,000 Australians, most of whom had underlying coronary artery disease.[3]

At present, between 80 and 100 heart transplants are performed each year in Australia,[1] so even if heart transplantation is restricted to patients with evidence of end-stage heart disease, the ratio of potential recipients who might benefit from heart transplantation to donors is more than 25:1. For this reason, heart transplantation is offered only to patients who have:[4,5]

- end-stage heart disease;
- exhausted all alternative treatment options; and
- a life expectancy of at least 10 years after transplantation with a reasonable prospect of returning to an active lifestyle after transplantation.

2.1 Criteria for referral for assessment

The large majority of patients referred for heart transplantation have a history of chronic heart failure. In about 90% of cases, this is secondary to ischaemic heart disease or some form of dilated cardiomyopathy.[1,6] Less common forms of heart disease such as restrictive cardiomyopathy, congenital or valvular heart disease account for most of the remaining 10% of cases.

Chronic heart failure

Before referral for heart transplantation, patients with chronic heart failure should be established where possible on optimal medical therapy including maximally tolerated doses of angiotensin-converting enzyme inhibitors and beta-blockers. Patients who demonstrate poor tolerability of these agents (usually manifested as symptomatic hypotension, renal impairment or worsening heart failure) have a particularly poor prognosis and, in the absence of contraindications, should be referred for heart transplant assessment. Similarly, patients who require repeated hospitalisation for decompensated heart failure and who need repeated or chronic administration of intravenous diuretic or inotropic therapy to achieve fluid control and haemodynamic stabilisation also have a particularly poor prognosis[7] and should be referred for heart transplant assessment if otherwise suitable. Some of these patients will ultimately require permanent mechanical circulatory support as a 'bridge' to transplant. Currently, in Australia or New Zealand, approximately 25% of heart transplants are performed on patients who are supported with ventricular assist devices.[1]

Many patients with chronic heart failure undergo implantation of an automatic implanted cardioverter defibrillator (AICD) either as primary or secondary prevention against sudden death.[8] A substantial proportion of these patients will also be candidates for cardiac resynchronisation therapy (CRT; or biventricular pacing), particularly those with New York Heart Association (NYHA) Class III or IV symptoms.[8] Patients who fail to respond to CRT or who deteriorate after a period of improvement may also be candidates for heart transplantation. In addition, some patients with AICDs suffer frequent discharges from their devices. Transplantation may be a consideration for these patients if no alternative therapy can be found to control repeated firing of the defibrillator.

Other criteria for referral

A small proportion of referred patients present with disabling angina due to coronary heart disease that is not amenable to any form of revascularisation. This may be due to diffuse distal disease or failed previous revascularisation procedures.

2.1 Inclusion criteria

The essential indication for heart transplantation is the presence of end-stage heart disease for which no alternative therapy is available. End-stage heart disease may be manifested as:

- irreversible cardiogenic shock (eg complicating acute myocardial infarction);
- intractable symptomatic heart failure (NYHA Class III-IV) despite maximally tolerated evidence-based medical therapy;
- need for permanent mechanical cardiac support: ventricular assist device (VAD) or total artificial heart (TAH);
- frequent discharges from an AICD; or
- intractable angina despite optimal medical, interventional and surgical treatment.

All patients listed for heart transplantation have severely impaired quality of life and most have an estimated survival of less than 2 years without transplantation. Although the majority of patients who undergo heart transplantation have chronic heart failure, approximately 5% present acutely with cardiogenic shock complicating acute myocardial infarction, cardiac surgery (postcardiotomy syndrome) or myocarditis.[1] While some patients with cardiogenic shock will recover after a period of mechanical circulatory support, in others the heart shows no sign of recovery, in which case heart transplantation becomes the only treatment option offering any hope of long-term survival.[9]

When heart transplantation recommenced in Australia in 1984, the acceptable age range for referral was set arbitrarily between 5 and 50 years of age. The success of heart transplantation has resulted in these age boundaries being widened. At the time of writing, the youngest patient to undergo heart transplantation in Australia was 16 days old while the oldest patient was 71 years of age.[1] However, the presence of multiple comorbidities in patients over 70 years of age would be expected to exclude the majority of such patients from consideration.[4,5]

2.2 Exclusion criteria

Exclusion criteria for heart transplantation are as follows.

- *Active malignancy*[4] — active malignancies other than non-melanoma skin cancers remain an absolute contraindication to heart transplantation, however patients with 'cured' malignancy as evidenced by prolonged disease-free survival may be suitable for transplantation. A decision on whether or not to refer patients with a history of malignancy for heart transplant assessment needs to be individualised and generally should only be made in consultation with the oncologist caring for the patient.
- *Complicated diabetes*[10] — patients with diabetes mellitus with established microvascular complications, poor glycaemic control (HbA_{1c} > 7.5) or diffuse peripheral vascular disease are generally considered unsuitable for heart transplantation.[4,10] On the other hand, patients with diabetes without secondary end-organ disease (proliferative retinopathy, nephropathy or neuropathy) have undergone heart transplantation with excellent long-term outcomes.[10]
- *Morbid obesity*[11] — several studies have identified morbid obesity (body mass index [BMI] > 30 or >140 percent ideal body weight) as an independent risk factor for mortality,[11,12] with one study reporting a doubling of mortality by 5 years post-transplant for patients with a BMI > 30.[12] In light of these published findings, morbidly obese patients should be required to reduce their weight below a BMI of 30 before being considered for heart transplantation.
- *Uncontrolled infection* — as yet, there have been no reports of patients with human immunodeficiency virus (HIV) infection undergoing heart transplantation in Australia or New Zealand, but small series from overseas centres indicate that excellent survival can be achieved in selected patients.[13] Patients with chronic hepatitis B or C infection may also be suitable for heart transplantation depending on the presence and severity of chronic liver disease.[14,15] Patients colonised with multiresistant bacteria such as methicillin-resistant staph aureus (MRSA) or vancomycin-resistant enterococcus (VRE) have undergone successful heart transplantation,

however active systemic infection with these organisms would still be regarded as an absolute contraindication to heart transplantation.

- *Inability to comply with complex medical therapy* (eg chronic cognitive or neuropsychiatric deficits in the absence of a carer capable of taking on this role)[16,17] — noncompliance with medical therapy after heart transplantation is a powerful predictor of increased morbidity and mortality.[18]
- *Active substance abuse* (including smoking, excessive alcohol consumption and illicit drug use)[19,20] — recommencing smoking after heart transplantation has been identified as a risk factor for accelerated coronary artery disease, malignancy, kidney failure and death after transplantation.[20] 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.[21]
- *Irreversible degeneration/damage of other organ systems that precludes rehabilitation after heart transplantation* (eg advanced neurodegenerative disease, advanced rheumatoid arthritis, severe peripheral vascular disease not amenable to revascularisation)[4,5] — in cases where there is irreversible failure of multiple transplantable organs, combined organ transplantation may be a consideration (discussed in next section).[1,22–24]
- *Acute medical conditions* — a number of acute medical conditions may render a person temporarily unsuitable for heart transplantation. These include active peptic ulcer disease, acute pulmonary embolism and intercurrent systemic bacterial or fungal infection. Patients can be reconsidered for transplantation once these illnesses have resolved with appropriate medical therapy.

Exclusion criteria include any condition or combination of conditions that result in an unacceptably high mortality risk from heart transplantation or that preclude active rehabilitation after transplantation.[4,5,10,25]

Relative contraindications to heart transplantation include uraemia with calculated (or measured) glomerular filtration rate (GFR) < 40 mL/min,[25,26] hyperbilirubinaemia > 50 µmol/L,[26] intractable ascites with hypoalbuminaemia[27] and fixed pulmonary hypertension with transpulmonary gradient (TPG) > 15 mmHg or pulmonary vascular resistance (PVR) > 4 Woods Units after pulmonary vasodilator challenge.[26] 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.[25–27] 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'.[28] 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 3–6 month period in a large proportion of patients.[29]

Special circumstances/considerations

Heterotopic (piggy-back) heart transplantation

Historically, the vast majority of heart transplants have been performed orthotopically (ie the donor heart is implanted in the normal anatomical site of the recipient heart following its removal). Heterotopic or 'piggy-back' heart transplantation refers to the circumstance where the recipient heart is not removed and the donor heart is implanted in the chest and connected up 'in parallel' with the recipient so that the recipient now has two hearts pumping together. This may be considered in two clinical settings.

- Patients who meet the above criteria for heart transplantation and who have fixed pulmonary hypertension as evidenced by a TPG > 15 mmHg after vasodilator challenge.[30] Suitable agents for assessing acute pulmonary vascular reactivity include intravenous glyceryl trinitrate, intravenous prostacyclin and inhaled nitric oxide. 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 perioperative risk and the availability of other treatment options.

- 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.[31]

Combined organ transplantation (heart/lung, heart/liver, heart/kidney)

Combined organ transplantation can be carried out with the expectation of a similarly low perioperative mortality and reasonable life expectancy as heart-alone transplantation *in carefully selected individuals*.[22–24] Patients being considered for combined heart/other organ transplantation need to meet all standard criteria for heart transplantation plus have evidence:

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

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

Heart retransplantation

Heart retransplantation has rarely been performed in Australia and New Zealand.[1] The results of heart retransplantation for acute rejection and early graft failure are extremely poor.[32] These patients should not be considered for retransplantation. On the other hand, recent data from the registry of the International Society for Heart and Lung Transplantation indicate that selected patients undergoing heart retransplantation for late graft failure secondary to cardiac allograft vasculopathy can achieve excellent short and long-term survival.[6] These patients may be considered for heart retransplantation provided they meet standard eligibility criteria.

3 KIDNEY RECIPIENT SUITABILITY CRITERIA

The majority of patients with end-stage kidney failure would feel healthier, live longer and have a better quality of life with a kidney transplant, compared to staying on dialysis,[1–4] In Australia in the past 10 years, unadjusted 1-year patient and graft survival for primary deceased donor grafts has been stable at around 96%. Kidney transplant recipients have a 5-year survival rate of close to 90%.[5]

However, the number of kidneys available for transplantation from deceased donors is far short of the number of patients requiring a kidney transplant.[6,7] In most cases, only patients who have commenced dialysis are eligible to be listed on the transplant list. In 2008, 9,701 patients were already on dialysis and 2,476 new patients entered treatment programs for end-stage kidney failure.[6–8] In the same year, there were 1,298 patients on the waiting list for transplantation from deceased donors and just 459 kidneys available for transplantation.[8]

3.1 Inclusion criteria

Inclusion criteria for kidney transplantation are:

- end-stage kidney failure requiring dialysis;
- anticipated low perioperative mortality; or
- a reasonable postoperative life expectancy, defined as an 80% likelihood of surviving for at least 5 years after transplantation.

3.2 Exclusion criteria

Exclusion criteria for kidney transplantation are:

- an anticipated likelihood of less than 80% chance of surviving a minimum of 5 years following transplantation — comorbidities that might have a significant impact on the life expectancy of a kidney transplant recipient include cardiac disease, vascular disease, diabetes mellitus and malignancies;[9–14] or
- although advanced age in the absence of significant medical comorbidity is not necessarily a contraindication for kidney 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 comorbidities.[8]

Similar survival outcomes should be expected for recipients receiving combined transplants, where a kidney is transplanted with another organ (liver, pancreas, heart, and lung).

3.3 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 transplant unit (or their delegate) has the authority to have patients added to the active renal transplant waiting list.

4 LIVER RECIPIENT SUITABILITY CRITERIA

Liver transplantation is a highly successful treatment for selected patients with end-stage liver disease, small hepatocellular carcinomata and/or other metabolic disorders for which liver transplantation is curative. In such patients, patient-survival rates exceed 80% at 5 years post-transplant and median survival times are well beyond 10 years for both adults and children. The major limiting factor in providing this therapy is the number of deceased donors. Waiting list mortality rates in Australia and New Zealand are in the 10–15% range. Although live donor liver transplantation is offered in some centres this has had a limited effect on the overall waiting list mortality rate. Eligibility criteria are not likely to be extended or expanded unless there is an upturn in organ donor numbers.

4.1 Inclusion criteria

Inclusion criteria for liver transplantation are:

- chronic liver disease with life-threatening complications:
  - the principle indication in patients with end-stage liver disease is a Model for End-Stage Liver Disease (MELD) score of >15 in an adult or a Paediatric End-Stage Liver Disease (PELD) score of >17 (see Appendix G);[1]
  - patients may also be suitable candidates if they have small hepatocellular carcinomata (HCCs) that fulfil the University of California San Francisco (UCSF) criteria (see Appendix G);[2]
  - additional indications include:
    - liver disease that would result in a 2-year mortality rate of >50% without liver transplantation;
    - diuretic-resistant ascites;
    - recurrent hepatic encephalopathy;
    - recurrent spontaneous bacterial peritonitis;
    - recurrent or persistent gastrointestinal haemorrhage;
    - intractable cholangitis (in primary or secondary sclerosing cholangitis patients);
    - hepatopulmonary syndrome;[3]
    - portopulmonary hypertension;[3]
    - metabolic syndromes (with severe or life-threatening symptoms) that are curable with liver transplantation (eg familial amyloidosis, urea cycle disorders, oxalosis etc);
    - polycystic liver disease with severe or life-threatening symptoms; and
- acute liver disease unlikely to result in spontaneous recovery as determined by the King's College of London criteria (see Appendix G).

4.2 Exclusion criteria

Exclusions (medical or psychosocial) from listing include those conditions or circumstances that would make a post-transplant survival rate of >50% at 5 years unlikely. The following would be reasons to exclude patients from listing given this survivorship standard:

- malignancy (prior or current, except for HCC within UCSF criteria);[4]
- active infection (other than hepatitis B, hepatitis C, or HIV);
- coronary artery disease that is irremediable or associated with a poor prognosis;
- cerebrovascular disease that is irremediable or associated with a poor prognosis;
- severe metabolic syndrome (hypertension, morbid obesity, hyperlipidaemia, and type II diabetes, with or without obstructive sleep apnoea);[5]
- patients with alcoholic liver disease who experience social instability, alcohol problems in first degree relatives, who are <50 years old, have had repeated alcohol cessation treatment failures, find it difficult to comply with medical care, currently are polydrug abusers and/or who have a co-existing

severe mental disorder — such patients are very unlikely to remain abstinent in the post-transplant period;[6]

- tobacco use is a relative contraindication to liver transplantation (because of an increased risk of malignancy and cardiovascular disease);[7,8] and
- inadequate or absent social support is a relative contraindication to liver transplantation (because of an increased risk of non-adherence).[9,10]

4.3 Special circumstances

- *Hepatopulmonary syndrome* — Current evidence shows that patients with this condition who have a partial pressure of oxygen on room air of <40 mmHg have a high (unacceptable) perioperative mortality rate.[3]
- *Portopulmonary hypertension* — Current evidence shows that patients with this condition who have, despite treatment, a mean pulmonary artery pressure of >35 mmHg and a pulmonary vascular resistance of >250 dynes.sec.cm^{-5} (3.1 Woods units) have a high (unacceptable) perioperative mortality rate.[3]
- *Combined liver and kidney transplantation* — The United Network for Organ Sharing (USA) guidelines[11] suggest that combined liver-kidney transplantation only be offered to those liver disease patients with one of the following:
  - known chronic kidney disease requiring dialysis;
  - chronic kidney disease not requiring dialysis but with an estimated GFR of <30 mL/min and proteinuria of >3 g/day or with a GFR of <20 mL/min for >3 months;
  - acute kidney injury (including hepatorenal syndrome) not requiring dialysis but with an estimated GFR of <25 mL/min for >6 weeks; and
  - known metabolic disease including hyperoxaluria, atypical haemolytic uraemic syndrome with H factor deficiency or familial amyloidosis affecting primarily the kidney.

5 LUNG RECIPIENT SUITABILITY CRITERIA

Lung transplantation is a highly effective treatment for advanced lung disease.[1,2] Generally a 65% 5-year and 45% 10-year survival rate is expected following lung transplantation. It has been suggested that only 1 in 20 of those individuals with severe lung disease who might benefit from this technology will actually achieve transplantation.[1–5]

However, due to the scarcity of donor lungs, lung transplantation is offered only to patients who have a life expectancy of less than two years without transplantation, and who have no 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 guidelines.

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 contraindications, it follows that not all possible recipients will prove suitable for transplantation.[1,3–6]

Recent international guidelines were formulated with Australian input, and Australian and New Zealand units broadly follow these recommendations with local interpretation.[4,5]

5.1 Inclusion criteria

Inclusion criteria for lung transplantation are:

- respiratory failure despite optimal medical, interventional and surgical treatment; or
- poor quality of life, potentially with intractable symptoms and repeated hospital admissions (eg NYHA Class III-IV).

5.2 Exclusion criteria

Exclusion criteria for lung transplantation include (but are not limited to):

- active malignancy — in general a 5-year disease-free interval is prudent;
- irreversible significant dysfunction of other organs or body systems — combined organ transplant (eg heart/lung) may be a consideration, but patients must fit eligibility requirements for both organs and a plausible strategy for allocation must be in place;
- non-curable chronic infection;
- documented non-adherence, or inability to comply with complex medical therapy or office follow-up (eg untreatable psychological or psychiatric condition);[7–9] or
- substance addiction (eg alcohol, tobacco or illicit drug use) that is either active or within the last 6 months.

It is likely that the presence of multiple comorbidities in patients over 65 years of age will exclude the majority of such patients from consideration.[10]

6 PANCREAS AND ISLET

Pancreas transplantation is undertaken as a treatment for type 1 diabetes in two ways:[1]

- the whole solid pancreatic organ can be transplanted;[2] or
- the insulin producing islets that make up approximately 1–2% of the pancreas are separated out from the organ and can be used (usually infused into the liver).[3]

There are three units in Australia and New Zealand that perform solid organ pancreas transplantation (see Appendix E). The vast majority of solid organ transplants are undertaken as simultaneous pancreas and kidney transplants in recipients with both type 1 diabetes and end-stage (or near end-stage) renal failure.[4] A small minority of transplants are undertaken as solid organ 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.[2]

Pancreatic 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 Therapeutic Goods Administration (TGA) Clinical Trials Notification scheme.

Simultaneous pancreas (solid organ) and kidney transplantation

As the transplanting units are national centres often requiring referral from interstate, patients can first meet broad minimum eligibility criteria to allow referral and subsequent assessment by one of the three units. Further criteria must then be met in order for patients to be entered onto the transplant list.

This allows potential recipients to be seen and preliminarily assessed before their disease progresses to the point that they meet the final criteria for receiving the transplants. However, these criteria also prevent referral of patients who would ultimately be deemed unsuitable for combined kidney and pancreas transplantation. This is based on data demonstrating poor outcomes in subgroups of patients with, for example, significant cardiac disease,[5–7] increasing age[8] or obesity.[9] It is also based on feasibility, as is the case with significantly diseased iliac vessels bilaterally or with marked obesity, which make transplant surgery technically difficult or impossible.[9–11]

6.1 Criteria for referral to National Pancreas Transplant Unit

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

- type I diabetes with insulin dependence;
- GFR < 30 mL/min;
- absence of significant cardiac disease or adequately treated cardiac disease;
- patent iliac vessels bilaterally;
- BMI < 35; and
- age < 50 years (see below).

In the case of age, individual subjects > 50 years old may still be deemed eligible if they are otherwise very fit medically.[6,8] It must be taken into account however that patients will generally face a waiting time of approximately 2–3 years from listing to the time of transplantation. As advancing age appears to impact on the success of the combined transplant procedure,[6,8] alternative transplant options (eg kidney transplant alone, live kidney transplantation) also need to be strongly considered.[12]

In the case of cardiovascular and/or iliac vessel disease, referral may still be considered if the referring team have a strong expectation that these problems can be significantly resolved. Individual cases may need to be discussed directly with one of the national transplant units before they can make a decision to formally assess the patient's overall suitability.

6.2 Inclusion criteria — solid organ pancreas

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:

- insulin dependence deemed by the National Pancreas Transplant Unit to be reversible by pancreas transplantation;
- GFR < 15 mL/min and dialysis impending;
- absence of significant cardiac disease or adequately treated cardiac disease;
- patent iliac vessels bilaterally;
- BMI <30 (BMI 30–35 is a relative contraindication); and
- non-smoker or permanent cessation of smoking for more than 3 months.

The expectation that a solid organ pancreas transplant can fully reverse the need for insulin is based on a pattern of insulin deficiency rather than one of insulin resistance (signifying type 1 rather than type 2 diabetes). This is not always straightforward to determine but relies partly on the demonstration of absent or low C-peptide levels (a marker of native insulin production).[13,14]

Smoking has been found to adversely effect the success of the transplant procedure.[6,15] For this reason, patients are expected to demonstrate commitment to permanent smoking cessation before they can be transplanted.

While outcomes are significantly improved if patients can be transplanted early in the course of their renal disease progression,[16–18] the supply of organs and the need to maintain supply of kidneys to the kidney-only waiting list (where dialysis is a prerequisite) limits the ability to achieve this goal. The majority of patients will still be transplanted after they commence dialysis (GFR 0–10 mL/min by this stage) however some may be fortunate enough to be able to receive their transplants just prior to this need, when dialysis is impending (10–15%). The ability to do this is important, as the window of opportunity to transplant some of these patients can be small due to the multiple comorbidities present. The current mortality rate on the waiting list is approximately 10% per year, significantly higher than age-matched patients on the kidney-only waiting list.[19–22]

6.3 Exclusion criteria — solid organ pancreas

Exclusion criteria for pancreas transplantation are:

- exclusion criteria as per kidney-only transplant recipients (see Section 3.2);
- significant cardiac disease or inadequately treated cardiac disease;
- significant vascular disease;
- continuous antiplatelet therapy (generally with clopidogrel) that cannot be safely ceased to then allow surgery (eg recent coronary artery stenting at risk of thrombosis);
- significant psychiatric disease (affecting ability to cope and comply with surgery and treatment);
- demonstrated non-compliance with medical therapy; and
- addiction to non-prescription illicit drugs (eg narcotic or cannabis abuse).

6.4 Inclusion criteria — pancreatic islet

Patients are entered onto the national islet transplant list by recognised Clinical Islet Transplant Programs. Patients on the national Islet transplant list will be associated to a recognised 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 unsensitised and one sensitised patient (plasma renin assay [PRA] >10%) onto the active list at any one time.

Inclusion criteria for pancreatic islet transplantation are:

- type 1 diabetes for 5 years or more;
- age 18–65;

- severe hypoglycaemic unawareness (documented blood sugar level [BSL] < 3mmol/l without awareness) that has not responded to optimal conventional insulin therapy, as assessed by an endocrinologist;
- creatinine clearance > 75/mL/min/1.73m^2;
- serum creatinine < 130 μmol/L;
- 24-hr urine protein estimation < 300 mg/day;
- weight < 75 kg;
- the patient has read and signed the informed consent form;
- absence of donor reactive antibodies by Luminex and cytotoxic crossmatch;
- willingness to use effective contraception measures; and
- ability to understand the trial protocol and informed consent.

6.6 Exclusion criteria — pancreatic islet

Exclusion criteria for pancreatic islet transplantation are:

- weight > 75 kg;
- C-peptide response to arginine (5 g IV) — exclude any C-peptide greater or equal to 0.3 ng/mL at 2, 3, 4, 5, 7, and 10 minutes post infusion;
- creatine clearance < 75 mL/min/1.73 m^2;
- serum creatinine > 130 μmol/L;
- 24-hr urine protein estimation >300 mg/day;
- baseline haemoglobin (Hb) < 12 g/dL in women, or < 13 gm/dL in men;
- baseline lung function tests (LFTs) outside of normal range;
- insulin requirement > 0.7 IU/kg/day;
- glycated haemoglobin (HbA1c) > 12%;
- serum cholesterol > 10 mmol/l;
- systemic corticosteroid usage;
- treatment with terfenadine, cisapride, astemizole, pimozide, or ketoconazole (that is not discontinued prior to sirolimus administration);
- a positive pregnancy test or desire to fall pregnant within the timeframe of the trial;
- malignant disease other than localised and excised skin squamous cell or basal cell carcinoma;
- hepatic disease, including any form of active viral hepatitis, portal venous abnormality or cirrhosis;
- chronic pancreatitis;
- significant cardiac disease including ischaemic and valvular heart disease; and
- respiratory disease including clinically significant asthma, bronchiectasis or obstructive airways disease.

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Part B: Allocation protocols

7 ISSUES AFFECTING ALLOCATION OF ORGANS

The allocation of organs is a complex process, influenced by a number of factors including medical need, medical urgency, capacity to benefit, donor/recipient matching and logistical factors.

The allocation process and criteria vary depending on the type of organ to be transplanted, as outlined in this protocol. While the allocation of kidneys depends on how long somebody has waited and on their level of matching to the donor (as determined by a computer program called the National Organ Matching Service [NOMS]), many other factors are involved in the allocation of other organs. Because not all of these are related to medical need and capacity to benefit, the allocation process is difficult to follow with absolute equity and in practical terms, clinical decisions about allocation can be very difficult. Every attempt should be made to uphold the principles for allocation embodied in the NHMRC ethical guidelines (see page vi).

Transplant units should use donated organs as best they can, and balance medical need with the likelihood of successful transplantation, taking into account the following general criteria in considering potential recipients for organs:[1]

- length of time waiting for a transplant, taken from the time the illness progressed to a point that a transplant would be of immediate benefit;
- important medical factors, such as the closeness of tissue-matching and matching of organ quality;
- the urgency of the transplant given the likely degeneration of health without transplant therapy, especially if patient survival is immediately threatened by that degeneration;
- need in terms of how sick the patient is without transplant therapy, and the prospects for transplant therapy producing a better outcome; and
- logistical considerations in making the transplant available to the recipient within an appropriate timeframe (see below).

Logistical considerations

Depending on the organ type, logistical considerations may include factors such as:

- operation type;
- time of retrieval and operation room availability;
- location of recipients and/or donor (local, interstate);
- 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 and transplant;
- availability of intensive care unit (ICU) beds; and
- donor instability.

It is recognised that logistical considerations may override higher criteria (eg if there is limited ICU bed availability). In instances where logistics override higher criteria, this needs to be recorded as well as the specific logistical issue.

Organ retrieval mechanism

In general, the unit accepting the offer of a suitable organ 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 transplant units;
- liaison with the relevant donor coordinator to achieve a surgical starting time mutually acceptable to the donor hospital and all involved donor surgical teams; and
- ensuring that the retrieved organs meet medical standards for organ donation and are delivered in a safe and appropriate manner to the recipient unit's hospital.

Organ distribution and allocation

For most organs, organ allocation is organised according to both location and need. The time between removal of the donor organ from the donor and its implantation into the recipient is critical to post-transplantation outcomes. In order to minimise this ischaemic time, most donated organs are allocated within their home state.

- New Zealand donor organs may be offered to Australian units if there is no suitable recipient in New Zealand. The rotation of offers to those units is held by the New Zealand Donor Coordinators.
- For hearts, livers and lungs, distribution is organised and offers are made through the State Organ Donation Agency. If the home state declines the offer, non-home states are offered the organs based on a rotation kept by each state donor coordination team. If the first non-home state declines the offer, the next is asked until all units have been asked.
- The allocation of kidneys from deceased donors is determined by the NOMS, which is administered by the Australian Red Cross Blood Service (see Chapter 10). Kidneys are allocated through a two-level process: the national kidney exchange program (which tries to find suitable kidneys for patients who have the most difficulty finding a compatible kidney); and state-based allocation.
- Pancreas organs are offered to the national pancreas transplant units (see Chapter 13).

Individual patient allocation is decided, depending on patient characteristics and a range of other factors (see Chapters 9 to 13).

Urgent listings

Urgent listings exist for each organ type (except lung and pancreas) and can be used for patients who have a very high risk of death if they are not transplanted in the near future (eg patients with renal failure who no longer have dialysis access, or patients with severe cardiac failure who are unsuitable for mechanical support or develop life-threatening complications). Patients on the urgent listing are offered the next compatible donor organ arising anywhere in Australia and New Zealand.

Donor issues

Standard and extended criteria for donor suitability exist for each organ type, as specified in Chapters 9 to 13 below. Standard criteria relate to donor characteristics associated with the best outcomes after transplantation; for example, age less than 50 years and no comorbidities.

In order to increase the availability of donor organs, expanded eligibility criteria have been developed that include extended criteria for donation. These are donor characteristics that are associated with increased short and/or long-term morbidity and mortality after transplantation; for example, age over 65 years, longer ischaemic time and comorbidities.

8 GENERAL ORGAN DONOR INFORMATION

8.1 Organ donation

The allocation protocols in this document concern organs for transplantation from deceased donors where death has been determined using the 'brain function criterion' (donation after brain death or DBD). DBD remains the preferred donation pathway because it results in the retrieval of more organs of better quality. An alternative pathway to donation for patients for whom DBD is not possible or appropriate, donation after cardiac death (DCD)(also known as non-heart-beating donation or donation after cardiocirculatory death), is discussed in a separate document, *National Protocol for Donation after Cardiac Death,* to be issued by the Australian Organ Donation and Transplantation Authority in 2010.

Prerequisites to deceased organ donation

Before organ donation can take place:

- the donor must have been declared dead by a competent authority within the donor's jurisdiction; and
- consent to organ donation must be given and documented according to the laws and regulations in force at any time of donation in the jurisdiction of the donor's hospital.

It is the responsibility of the hospital authorities, and the donor coordinator and all donor surgeons in charge or donor surgical teams, to confirm that these laws and regulations have been fully complied with and documented appropriately.

8.2 Medical history

Background medical history

The donor's medical history must be known and recorded in the hospital records. Specific attention must be paid to:

- past medical history and past social history, including smoking and alcohol intake;
- history of risk factors within the past 12 months for the transmission of HIV, hepatitis B and hepatitis C:
  - — intravenous drug abuse, tattoos and body piercing;
  - — active homosexuality/bisexuality or heterosexual contact with a high risk partner;
  - — note should be taken of the national guidelines for blood transfusion;
- diabetes in any donated organ;
- history of risk factors for the transmission of Cruetzfeld-Jacob disease:
  - — family history of early dementia;
  - — use of pituitary hormone extract;
  - — notification of treatment with pituitary hormone extract;
- any other medical factor that may influence a recipient's decision to accept the donation; and
- history of malignancy.

Current medical history

Current medical history must include the diagnosis of the cause of death and knowledge of the hospital course, together with the current clinical status. The standardised Australian Transplant Coordinators Association (ATCA) medical history questionnaire will be completed for all donors. Specific attention must be paid to:

- clinical, laboratory or investigative indicators of transmissible neoplastic disease (note the report of the Consensus document of the Council of Europe 1997);

- immediate past and current cardiovascular status;
- medication given to the donor;
- all surgical interventions undertaken during the admission; and
- untreated bacterial, viral or fungal infection.

Absolute contraindications for organ donation

Absolute contraindications for organ donation include:

- any history of malignant melanoma;
- any history of metastatic malignancy;
- other non-curable malignancy (curable malignancy such as localised small kidney tumours, localised prostate cancer, colon cancer >5 years previously may be considered after careful risk/benefit analysis); and
- active HIV infection.

8.3 Investigations

Mandatory investigations

- Blood group for ABO and Rhesus
- Human immunodeficiency virus (HIV) antibody
- Hepatitis B surface antigen (see detailed guidelines)
- Hepatitis B core immunoglobulin G (IgG) antibody (see detailed guidelines)
- Hepatitis C antibody (see detailed guidelines).

Recommended investigations

- Cytomegalovirus (CMV) IgG antibody
- Epstein Barr virus (EBV) capsid IgG antibody
- Beta human chronic gonadotrophin hormone in female of child bearing age dying from unexplained intracerebral haemorrhage
- Human T-lymphotrophic virus (HTLV) I and II antibody, especially for donors from high risk groups
- Testing for Hepatitis C and HIV using polymerase chain reaction (PCR) assays would be highly desirable for donors in high-risk categories either from their medical history or laboratory tests
- A postmortem examination.

8.4 Hepatitis B testing and use of hepatitis B positive donor organs

Recent data has led to re-examination of guidelines for testing for hepatitis B in donated organs and tissues for transplantation. Guidelines of the TSANZ Expert Advisory Panel in August 1997,[1] recognised that tests for hepatitis B are subject to a degree of false-positives and false-negatives and that the precise details of the tests employed vary from manufacturer to manufacturer and with developments over time.

Hepatitis B testing

	Persistent infection	Past infection	Vaccinated	Uncertain
Hepatitis B surface antigen (HBsAg)	+	–	–	–
Hepatitis B surface antibody (HBsAb)	–	+ **or** –	+	–
Hepatitis B core antibody (HBcAb)	+	+ **or** –	–	+

A positive result for HBcAb alone may indicate:

- longstanding past infection with eventual loss of HBsAb;
- persistent infection without detectable HBsAg;
- acute phase infection after disappearance of HBsAg and before appearance of HBsAb; and
- false-positive test result.

Transplantation from the hepatitis B surface antigen or core antibody positive donor

- *Liver transplantation*: It is clear that hepatitis B is frequently transmitted by transplantation of livers from donors with this status.[2–8] Recent data suggest that transmission of infection can be prevented by use of lamivudine therapy in the recipient.[9–11]
- *Other solid organ transplantation*: There are fewer data on transmission of infection from HBcAb+ donors after transplantation of other solid organs or tissue[2,12-14]. Published studies suggest that the risk of development of clinical hepatitis in transplant recipients of organs from HBcAb+ donors is very low.
- *Tissue transplantation*: There are data available on the use of heart valves from HBsAg+ donors in both immune and non-immune patients.[15]

Recommendations

- *All potential liver donors* must be tested for HBsAg and HBcAb.
  - HBsAg+ donors represent the highest risk for transmission. These donors should be excluded as donors for Hepatitis B negative recipients, other than in exceptional circumstances.
  - HBcAb+ donors should be considered for HBsAg+ recipients in units with protocols that use Lamivudine and Hepatitis B immunoglobulin cover for transplantation.
  - HBcAb+ donors may be considered for HBsAg– recipients, provided informed consent is obtained and anti-hepatitis B antiviral therapy is used in the recipient.
- *All potential donors of hearts, lung, kidneys, pancreas or other vascularised organs* except the liver, must be tested for HBsAg.
  - Organs from HBsAg+ donors must not be used for HBsAg– recipients.
  - There is no current evidence of transmission of hepatitis B by HBsAg– donors in Australia.
  - There is a single case report of 1 of 42 kidney recipients of HBsAg– HBcAb+ kidneys becoming infected with hepatitis B.[2]
- *Non-liver organ recipients* of organs from donors known to be HBsAg– but HBcAb+ should ideally be immune and/or vaccinated to Hepatitis B and must be transplanted only after specific informed consent has been given.
- *All donors of banked and non-vascularised tissue,* including cornea, bone and heart must be tested for HBsAg and should be tested for HBcAb. The non-urgent and non-life threatening nature of the indications for tissue transplantation require that all HBsAg+ donors represent a potential risk for transmission of hepatitis B and their tissues must not be used. Donors who are HBsAg– but HBcAb+ represent an unknown risk for the transmission of hepatitis B and their tissues should not be used other than in exceptional circumstances. If tissues from positive donors are considered, prophylactic treatment of the recipient should be considered and informed consent must be obtained.

8.5 Hepatitis C testing and use of hepatitis C positive donor organs

Prevalence of organ donor anti-hepatitis C antibody positivity and transmission risk from organ donors

Organ donors in the USA have a mean prevalence of approximately 5% anti-hepatitis C antibody (Ab) positivity and rates in Australian or New Zealand donors are similar. These figures are significantly greater than random blood donors (0.3%). Not all anti-hepatitis C Ab+ subjects are currently infected. It has been estimated that approximately 50% of hepatitis C donor organs are hepatitis C PCR+.[16,17] This figure may be an overestimation depending on number of false-positive results in the organ donor cohort. It is only hepatitis C PCR+ donors who have been documented to transmit infection[18] and up to 100% of these donors transmit infection to recipients.[16] There are no demographic data to distinguish anti-hepatitis C Ab+ PCR+ versus anti-hepatitis C Ab– PCR– subjects.[16]

Natural history of hepatitis C infection in non-liver recipients

There is evidence that hepatitis C positive recipients of kidney, pancreas or heart transplants have significantly worse long-term outcomes following transplantation than non-infected subjects.[19,20] There are few data as yet on the natural history of HCV infection after lung transplantation.[21] In general it is difficult to dissect out from the literature hepatitis C positive subjects who were HCV Ab+ pre-transplant from those who acquired the infection post-transplant.

A Hepatitis C Positive Register exists to allow transparent and equitable allocation of kidneys from hepatitis C positive donors to hepatitis C ribonucleic acid (RNA)+ recipients who would like to be considered for such kidneys (see Chapter 10).

Natural history of hepatitis C infection post liver transplant

There are data to suggest that hepatitis C infection in this setting may result in significant liver disease. However, 5-year survival rates do not as yet show significant differences between hepatitis C Ab+ and Ab– recipients.[22] There are data to suggest that subjects with higher pre transplant and post-transplant viral loads have poorer outcomes[23,24] and earlier data indicated that patients who require liver transplant with genotype 1b also have poorer outcomes,[22] but this has not been supported in all studies.

Use of hepatitis C positive donor livers

Some data suggest that recipients of hepatitis C positive livers do not have a worse outcome.[25–26] Indeed when hepatitis C positive grafts are transplanted into hepatitis C positive recipients with different genotypes, the recipients who develop the donor genotype have a better outcome.[27]

Conclusions from the current data

- *Organs from hepatitis C Ab+ donors should not be used for hepatitis C negative recipients unless there are exceptional life-threatening circumstances*: The combination of a significant transmission risk combined with increasing data on poorer long-term outcome, if transmission does occur, leads to this conclusion.
- *Organs from hepatitis C Ab+ donors may be used for non-liver hepatitis C Ab+ recipients who are PCR+:* Hence the PCR status of recipients should be known. The use of hepatitis C Ab+ donor organs for hepatitis C Ab+ PCR+ recipients should not be dismissed. The theoretical risks involve aspects such as different hepatitis C genotypes and viral loads between recipient and donor that may influence outcomes. More data are required but it is not unreasonable to use such donors in certain circumstances and with the specific informed consent of the recipient including clear information on the potential risks.

- *Livers from hepatitis C Ab+ donors may be used for hepatitis C PCR+ recipients:* The waiting list for liver recipients in Australia is increasing and hepatitis C-related cirrhosis is the main indication for liver transplantation (approximately 30% of all adult recipients). The evidence that excluding hepatitis C Ab+ donors, 50% of whom may be PCR–, will affect outcomes is not available. The theoretical risks of different viral loads and genotypes should be studied. However, recent data suggest that this does not alter outcomes (changing to donor genotype may even be beneficial). Specific informed consent of the recipient would be required with provision of clear information of the potential risks.

Recommendations

- Use of anti-hepatitis C Ab+ donors for hepatitis C Ab– recipients (all tissues, heart, kidney, lung, pancreas, liver) is NOT recommended).
- Use of anti-hepatitis C Ab+ donors for hepatitis C Ab+ PCR– recipients is NOT recommended.
- Use of anti-hepatitis C Ab+ PCR+ donors for hepatitis C Ab+ PCR+ non-liver recipients may be considered following specific informed consent.
- Use of anti-hepatitis C Ab+ donors for hepatitis C Ab+ PCR+ liver recipients should be considered.

9 DONOR HEART ALLOCATION

9.1 Heart donor suitability criteria

With the exception of 'domino' hearts (discussed below), all hearts for heart transplantation in Australia and New Zealand are obtained from DBD donors. Internationally, successful heart transplants have been reported using hearts retrieved from DCD donors,[1] however the use of these organs raises major ethical and medico-legal issues and is currently not recommended. The quality of donor hearts varies enormously and historically only about 40% of hearts retrieved from DBD donors have been considered acceptable for transplantation. With improvements in donor management and heart preservation, it is expected that the proportion of transplantable hearts retrieved from DBD donors will increase.

Donor hearts are stratified according to the standard or extended criteria below.

Table 9.1 Standard criteria for heart donation

General organ donor criteria	See Chapter 8
Age < 50 years	
No known significant cardiac disease	If in doubt contact heart transplant unit
Not dependent upon high-dose inotropes	Noradrenaline < 0.2 μg/kg/min or equivalent

Table 9.2 Extended criteria (marginal) for heart donation

Donor age > 50 years	Risk of death after heart transplantation increases progressively with donor age > 30 years. A donor age of 50 years is associated with a 50% increase in the relative risk of death at 1 year post-transplantation compared with a donor aged 30 years. The relative risk of death at 1 year post-transplantation rises to 80% at a donor age of 60 years[2]
Anticipated ischaemic time > 360 minutes	Risk of death after heart transplantation increases progressively with ischaemic time > 240 minutes Ischaemic time > 360 minutes is associated with a 30% increase in the relative risk of death at 1 year post-transplantation[2]
Donor requiring high-dose inotropic support	Noradrenaline > 0.2 μg/kg/min or equivalent[3]
Donor graft dysfunction on echo	Left ventricular ejection fraction (LVEF) < 50%, major wall motion abnormality[4]
Donor comorbidities	eg donor hepatitis B or C positive or high risk behaviour [4,5]

It is expected that all heart transplant units in Australia and New Zealand will make use of both standard and extended criteria donors. The acceptability of extended criteria donors to potential heart transplant recipients should be discussed at the time of transplant listing with both the patient and the patient's carer (rather than on the day of transplantation). Informed consent should be obtained on the day of transplantation when there is a potential risk of transmission of donor infection (eg donor positive for hepatitis B or C).

9.2 Donor information required for allocation

Table 9.3 Donor information required for heart allocation

1. Blood group	
2. Body weight	
3. Approximate height	
4. Laboratory tests	General organ donor criteria for viral studies (see Chapter 8) HIV, HBsAg, HBcAb, hepatitis C, cytomegalovirus (CMV)
5. Investigations	Current chest x-ray Electrocardiogram (ECG) done after cessation of brain function Echocardiogram (desirable)

9.3 Organ allocation and distribution

- The donor coordinator of the relevant state donor coordination agency is responsible for identifying potential cardiothoracic organ donors and notifying the transplant coordinator for the corresponding heart transplant unit.
- 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
NSW, ACT	NSW
VIC, TAS	VIC
QLD	QLD
WA	WA

- If the home state declines the offer, the donation offer is made on rotation to non-home state recognised heart transplant units, with a 20-minute response time. In Victoria, the donor coordinators keep a record of the rotation between the two units.
- Donor heart offers from South Australia and the Northern Territory are offered on the same rotation as for non-home state offers. South Australian or the Northern Territory patients who require heart transplantation are referred to interstate heart transplant units, usually Melbourne or Sydney. New Zealand heart donor offers that are declined by the New Zealand Heart Transplant Unit may be offered by New Zealand to recognised heart transplant units in the eastern states.

9.4 Individual patient allocation

Donor hearts are allocated according to the following criteria. Decisions about each individual offer and waiting list management are the responsibility of the recognised heart transplant unit.

Table 9.4 Donor heart — individual patient allocation criteria

1. ABO compatibility*	Except paediatric patients aged < 12 months[6]
2. Negative lymphocytotoxic cross-match*	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[7]
4. Urgent status**	
5. ABO identity	
6. Recipient waiting time	
7. Logistical considerations	

Notes:

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

** *Urgent status for heart transplantation* — Under some circumstances (eg when transplantation candidates are unsuitable for mechanical support or develop life-threatening complications while on support) and the patient's survival is estimated to be days or weeks without transplantation, the patient may be placed on an urgent list.

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 coordinators 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 2 weeks of notification. Each transplant unit will be allowed a maximum of three 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) and other factors as listed on page 22, and in some situations may override criteria 4–6.

Where possible, patients waiting for heart transplantation are managed at home (which is where the majority of patients prefer to be if they are well enough), however, if it is determined that a patient's residence is too remote to allow them to be transferred to the transplant unit on the day that a donor heart becomes available then arrangements will be made for the recipient to be accommodated close to the hospital.

Domino heart allocation

Domino hearts are hearts donated by recipients of heart-lung transplants (HLTx). For most HLTx recipients both the heart and lungs are severely dysfunctional and require replacement, however some HLTx recipients have severely impaired lung function but intact heart function. In these cases, the excised heart may be suitable for transplantation into a patient who requires heart transplantation. With the advent of bilateral lung transplantation, domino heart transplantation has become a rare occurrence. Domino heart transplants are unique among heart transplants as they are the only circumstance where the heart donor is a living donor.

Domino hearts donated by a HLTx recipient should be donated according to the relevant jurisdiction's laws on living donation and allocated to a medically appropriate recipient on the waiting list of that heart/lung transplant unit. In the event that there is no suitable heart recipient within the heart/lung transplant unit, the domino heart should be offered on to the non-home state recognised heart transplant units using the same rotation as for deceased donor hearts.

10 DONOR KIDNEY ALLOCATION

10.1 National Organ Matching System

The major criteria used by the National Organ Matching System (NOMS) to decide which patient on the transplant list will be allocated a donated kidney are:

- the blood group (most kidneys are allocated to a patient who is the same blood group as the donor);
- how long the patient has been on dialysis;
- tissue-type matching with the donor;
- whether the patient has many antibodies against other people's tissue types; and
- whether the patient is a child (paediatric patients get priority).

10.2 Allocation principles

Allocation of kidneys is based on the following principles.

- Donated kidneys go through a two-level allocation process coordinated through NOMS:
  - the National Kidney Interstate Exchange program, which tries to find suitable kidneys for patients who have very specific clinical needs and also maintains a balance in donor kidneys between the states; and
  - state-based allocation — the majority of kidneys (approximately 80%) are allocated within the state in which they are donated.
- The rules for the national as well as each state's allocation protocol are transparent and available to all potential recipients.
- At least 30% of all locally allocated kidneys are allocated according to waiting time (rather than human leukocyte antigen [HLA] matching).
- Waiting time is taken from the commencement of dialysis and not from time of admission to the waiting list.
- Each transplanting region has 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 deceased donor kidney.
- Paediatric recipients are few in number, and have special needs with respect to physical and psychological development that are best met by transplantation.[1,2] 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 RNA+ recipients who would like to be considered for such kidneys.[3]

It is anticipated that the medical quality of donated kidneys will continue to fall, as more kidneys are received from extended criteria donors. This poses questions about how to most fairly utilise these kidneys, while trying to also maximise the outcomes for all transplanted kidneys.

The Renal Transplant Advisory Committee (RTAC) is exploring a local definition for extended criteria donors, which might encompass approximately the poorest quality 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.[4–6]

10.3 Allocation algorithms

National Interstate Exchange Algorithm

The first level of matching in the NOMS database occurs at a national level and involves every patient on the waiting list in Australia. It is designed primarily to help patients with high levels of antibodies against other tissue types, as it is difficult to find a suitable kidney for these patients and their outcome is likely to be better if they are receive a very well matched kidney.[7,8] If a difficult to match patient is identified in NOMS as a very close match to the donor kidney, this kidney can be sent to them from anywhere in Australia. The 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. About 20% of all kidneys are allocated according to this Interstate Exchange program.

State-based allocation algorithms

The remaining 80% of donated 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 aims to achieve a similar outcome, although they use slightly different formulae to do this. The computer first looks for patients who are very closely matched with the donor.[7] In many cases there is nobody with a very close match and all of the matches are either average or poor. In this case the matching is ignored, as there is little additional advantage from this level of match. The kidney is allocated to the patient of the same blood group who has been waiting the longest. This also helps to avoid some patients from being disadvantaged by excessive waiting times. All states ensure that their algorithm results in a minimum of 30% of patients receiving kidneys on the basis of time waited.

Different states need differing allocation algorithms because of their different sizes and therefore different numbers of people on their waiting lists. Identical formulae would lead to different results in the different states; in particular, more kidneys would be allocated because of a good match in states with more people on the waiting list, leaving fewer kidneys to be allocated on the basis of time spent on dialysis. If there are too few kidneys allocated to those who have been waiting a long time, some patients, particularly those from ethnic minority groups who have different tissue typing to that which is common among donors can be greatly disadvantaged. Furthermore, some studies suggest that prolonged waiting times on dialysis are associated with poorer long-term graft survival after transplantation.[9,10]

The mathematical details of these algorithms are shown in Appendix F.

Exceptions

Some types of kidneys are only allocated within the state in which they are donated and therefore only the state algorithm is used for their allocation. This situation arises when it is particularly important to transplant the kidney quickly, or where there are technical issues that make it safer for the local surgical team who removed the kidney to also be involved in transplanting the organ. Examples include:

- DCD donor kidneys, which are particularly prone to delayed functioning;[11,12] the more quickly these can be transplanted, the better the chance of good early function and a positive long-term outcome;[13] and
- kidneys removed from living patients as a treatment for renal cancer; a small cancer is removed, the kidney repaired, and the kidney transplanted into a needy recipient.[14]

Simultaneous kidney and pancreas transplantation offers the best clinical outcomes for patients with type 1 diabetes mellitus.[15] 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 high levels of antibodies they 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.

All states have an "Urgent" category for transplantation. This is very rarely used, but is used for patients who have a very high risk of death if they are not transplanted in the near future. The vast majority of such cases are for patients who have run out of dialysis access, meaning that it may soon become impossible to keep them alive on dialysis.

11 DONOR LIVER ALLOCATION

11.1 Urgent patients

Any liver becoming available from a deceased donor within Australia or New Zealand is first to be allocated to patients listed as urgent. There are three separate categories as outlined in the table below.

Table 11.1 Categories of patients for urgent liver transplantation

Status 1	Patients suitable for transplantation with acute liver failure who are ventilated and in an ICU at risk of imminent death
Status 2a	Patients suitable for transplantation with acute liver failure from whatever cause who are not yet ventilated but who meet the King's College criteria as outlined in Appendix G. This includes patients who have acute liver failure because of vascular thrombosis in a liver allograft.
Status 2b	Paediatric patients suitable for transplantation who suffer from severe metabolic disorders or hepatoblastoma (after initial treatment) for whom a limited time period exists during which liver transplant is possible.

11.2 Non-urgent patients

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 ABO blood group identical recipient with the highest MELD or PELD score; and
- if not allocated according to MELD or PELD score then the following factors will be considered (and the reason for the variant allocation noted):
  - the presence of a patient on the list with HCC whose HCC MELD (see Appendix G) score exceeds the standard MELD score of other patients on the list of the same ABO blood group;
  - the quality of the donor liver[1–3] — poor quality donor livers may be utilised but may require transplantation into recipients with lower MELD scores to ensure success;
  - the presence of a paediatric patient on the waiting list in need of a split or reduced size liver provided the donor liver is of suitable quality;
  - if the donor is paediatric then for size reasons, paediatric recipients will have priority for that liver;
  - donor size — overly large size discrepancies result in poor outcomes; size matching may result in patients without the highest MELD or PELD scores being allocated a liver;
  - logistical concerns — transport, cold storage preservation time, surgeon and operating room staff skill mix and availability, along with the anticipated hepatectomy time may impact on allocation and result in patients without the highest MELD or PELD scores being allocated a liver; and
  - the presence of a patient on the waiting list who has a condition that will not result in a MELD, PELD or HCC MELD score that allows prioritisation — such patients will usually have severe, correctable extrahepatic disease that mandates some priority of allocation (eg familial amyloidosis, oxalosis, protein C deficiency) that is nevertheless a variance.

All allocation decisions are recorded for subsequent audit purposes.

12 DONOR LUNG ALLOCATION

12.1 Lung donor suitability criteria

Table 12.1 Suitability criteria for lung donation[1–5]

General organ donor criteria	See Chapter 8
Age 5–65 years	
No significant untreatable lung disease	Also no known significant pleural disease for DCD lung donation
Arterial blood gases on 100% fractional inspired oxygen (FiO_2) and 5cm positive end-expiratory pressure (PEEP) >250mmHg	Or equivalent partial pressure of oxygen in the blood (PaO_2)/Fio_2 ratio

12.2 Donor information required for allocation

Table 12.2 Donor information required for lung allocation

1. Accurate lung disease and treatment history	Especially smoking (cigarettes and cannabis), 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% FiO_2 and 5cm PEEP Chest x-ray and lung field measurements within 24 hrs Fibreoptic bronchoscopy (if possible) Donor/recipient lymphocytotoxic cross-match Donor/recipient CMV serology Donor/recipient EBV serology (if available)

12.3 Organ allocation and distribution

- The recognised lung transplant unit in the home state is offered the donation as detailed below and given 20 minutes to respond to the offer.

State of donor hospital	Lung Transplant Unit
NSW, ACT	NSW
VIC, TAS	VIC
QLD	QLD
WA	WA
SA, NT	On rotation through above states

- If the home state declines the offer, the lung donation offer is made on to the non-home state recognised lung transplant units, with a 20-minute response time, based on a rotation kept by each

state donor coordination team. 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).

12.4 Individual patient allocation

The allocation of donor lungs is complicated by 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.[4,6–8] Donor lungs are allocated considering the following criteria.

Table 12.3 Donor lung — individual patient allocation criteria

1. ABO compatibility
2. Size compatibility
3. Absence of a positive T-cell cross-match
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

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:
  - Extracorporeal membrane oxygenator (ECMO)
  - Invasive mechanical ventilation
  - Non-invasive ventilation
  - High-flow O_2 requirement
  - Low-flow O_2 requirement
  - Prolonged or recurrent hospitalisation
  - Other support devices such as continuous intravenous therapies
- **Rapidity of deterioration** includes, but not limited to
  - change in NYHA functional Class or MRC grade
  - significant fall in lung function parameters
  - significant fall in PaO_2
  - significant rise in partial pressure of carbon dioxide in the blood ($PaCO_2$)
  - 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

** Logistical considerations include operation type (lobar, single, bilateral, heart/lung), availability of required team members for the retrieval, lung transplant(s) and related cardiac transplants (paired donor heart or domino heart transplant) as well as the other factors listed on page 22.

*** Consideration of 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.

13 DONOR PANCREAS AND ISLET ALLOCATION

13.1 Pancreas donor suitability criteria

Similar to the selection process for other organs, donor selection criteria for pancreas transplants are based on factors that can have an adverse impact on the success of the procedure,[1–5] as well as on general factors required for safety (eg infection risk, malignancy).

Table 13.1 Standard criteria for pancreas donation

General organ donor criteria	See Chapter 8
Age to 3–45 years	For paediatric donors, body weight > 25kg[6]
No known diabetes mellitus or insulin dependence	
No known pancreatic trauma	May be considered for separated islets
No history of alcoholism or chronic pancreatitis	

Table 13.2 Extended criteria for pancreas donation after cardiac death[3,7]

Suitable DCD organ donor	
Age to 35 years	
No known diabetes mellitus or insulin dependence	
No known pancreatic trauma	May be considered for separated islets
No history of alcoholism or chronic pancreatitis	
Maximum ischaemia time from withdrawal of treatment to organ perfusion < 30 minutes	
Liver deemed suitable for transplantation	Expected to correlate with good pancreatic integrity

13.2 Donor information required for allocation

Table 13.3 Donor information required for pancreas allocation

1. Blood group	ABO compatibility: absolute requirement
2. Body weight	>25kg and <100kg
3. Body height	
4. Abdominal girth	
5. History of donor haemodynamic status	Ionotrope use, blood pressure
4. Laboratory tests	General organ donor criteria for viral studies HIV, HBsAg, hepatitis C, CMV Electrolytes, glucose, amylase and/or lipase Current use of insulin, dextrose and steroids

Lymphocytoxic cross-match: peak and current serum negative test is required for appropriate recipient selection however this information is not required at the time of allocation (usually available after organ allocation to Transplant Unit).

HLA typing is not required for allocation (usually available after organ allocation to transplant unit).

Table 13.4 Donor information required for pancreatic islet allocation

1. Blood group	
2. Body weight	
3. Approximate height	
4. Abdominal girth	
5. History of donor haemodynamic status	Ionotrope use, blood pressure
4. Laboratory tests	General Organ Donor Criteria for viral studies HIV, HBsAg, HBcAb, hepatitis C, CMV Electrolytes, glucose, amylase and or lipase Current use of insulin, dextrose and steroids

13.3 Organ retrieval mechanisms

Due to the small number of pancreas transplant units, geographic considerations as well as local expertise need to be taken into account in the process of retrieval. In some cases the accepting team (National Pancreas Transplant Unit) will perform the retrieval. Where circumstances make it possible and/or favourable for the local teams to be involved in the process of retrieval and delivery, this will also be considered. Pancreas donations in Western Australia, Queensland and South Australia may involve the local teams, avoiding the need for the staff from the pancreas units to travel interstate for the retrieval process.

13.4 Organ allocation and distribution

Donor pancreas organs arising in New Zealand are initially offered to the Auckland National Pancreas Transplant Unit. If the Auckland Unit is unable to use the organs (eg no suitable recipient, availability of appropriate surgeons for either retrieval or transplant procedure) then the Australian National Pancreas Transplant Units (Westmead and Monash) will receive the offer.

Donor pancreas organs arising in NSW, ACT, Queensland, South Australia and Western Australia are initially offered to the Westmead National Pancreas Transplant Unit for consideration of simultaneous kidney and pancreas transplantation. If the Westmead Unit is unable to use the organs (eg no suitable recipient, availability of appropriate surgeons for either retrieval or transplant procedure) then the Monash Unit will receive the offer, followed by the Auckland Unit and the Islet Units (Westmead followed by VIC/SA).

Donor pancreas organs arising in Victoria or Tasmania are initially offered to the Monash National Pancreas Transplant Unit for consideration of simultaneous kidney and pancreas transplantation. If the Monash Unit is unable to use the organs (eg no suitable recipient, availability of appropriate surgeons for either retrieval or transplant procedure) then the Westmead Unit will receive the offer, followed by the Auckland Unit and the Islet Units (VIC/SA followed by Westmead).

Allocation of the second donor kidney in the case of simultaneous pancreas and kidney transplantation is discussed in Chapter 10.

13.5 Individual patient allocation

Patients are transplanted in order of referral for assessment within each blood group, within each transplantation unit. The decision about each individual offer and transplant list management are the responsibility of the recognised Pancreas Transplant Unit.

Each solid organ pancreas transplant unit allocates organs to the patient waiting the longest period on the transplant list, who is deemed suitable and ready for transplantation.

Each islet transplant program allocates islets to the patient waiting the longest period on the transplant list, who is deemed suitable and ready for the islet preparation made available for transplantation.

Where donor pancreas organs meet the appropriate criteria for both solid organ and islet transplantation, they are first offered for solid organ transplantation. If the pancreas is not accepted by the National Pancreas Transplanting Units for this purpose, then the pancreas can be offered to the Islet Transplant Units.

There is no urgent classification for pancreas or islet recipients.

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Appendices

A MEMBERSHIP OF THE WORKING PARTY

Chairperson	Peter Macdonald
Heart	Peter Macdonald and Paul Jansz
Kidney	Scott Campbell
Lung	Greg Snell
Liver	Stephen Munn
Pancreas and islet	Jeremy Chapman OAM (TSANZ Pancreas Islet Committee to 30 September 2009)
	John Kanellis (TSANZ Pancreas & Islet Standing Committee from 1 October 2009)
Executive Officer	Rosemary Allsopp
Senior Project Officer	Maria-Jose Velasco
Technical writers	Elizabeth Hall and Jenny Ramson (Ampersand Health Science Writing)

Special thanks:

Bernadette Tobin

Michael Fink

Aviva Rosenfeld, Executive Officer TSANZ

The Members of TSANZ Council

B 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 transplantation 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.

C PROCESS REPORT

Background

The Australian Organ and Tissue Authority (the Authority) was established on 1 January 2009 with the aim of creating a nationally consistent and coordinated approach to organ and tissue donation and transplantation.[4] Prior to the creation of the Authority, the allocation of organs for transplantation was guided by state-specific guidelines, local hospital protocols, and procedures and protocols developed by the TSANZ and the Australian Transplant Coordinators Association (ATCA). The variability between different transplant centres and across state and territory jurisdictions created concern among some stakeholders regarding the equity and transparency in the eligibility and allocation criteria of organs for transplantation.

On 16 January 2009, as part of the Australian Government's reform package for organ and tissue donation for transplantation, the TSANZ obtained funding from the Australian Department of Health and Aging (subsequently transferred to the Authority) to enhance the role of its Clinical Standing Committees to convene a multidisciplinary group of transplantation clinicians, health-care professionals, and consumer representatives to develop a nationally uniform eligibility guidelines and allocation protocols for organ transplantation.

The Working Party

The Working Party that coordinated the revised criteria comprises a panel of transplantation clinicians in the speciality fields of Cardiology, Nephrology, Respiratory Medicine, and Surgery. As part of the funding, an Executive Officer and a Senior Project Officer were employed by the TSANZ to support the development of the revised criteria. Technical writers from Ampersand Health Science Writing were contracted after the initial consultation process to redraft and edit the second version of the document (see Appendix A).

Development

The TSANZ Clinical Standing Committees convened for a two-day workshop on 19–20 March 2009. The enhanced role of the TSANZ Clinical Standing Committees made it possible for a multidisciplinary group across all states and territory jurisdictions to revise the existing eligibility and allocation criteria for organ transplantation (Standing Committee terms of reference are given in Appendix B). The revision process incorporated further input in June 2009 by the TSANZ membership at the TSANZ Annual Scientific Meeting.

The eligibility guidelines and allocation protocol for organ transplantation have been revised according to current best practice, experience, and national data obtained from transplantation registries. Where possible, the criteria are supported by the best available scientific evidence.

Consultation

In keeping with the multidisciplinary approach, the draft document underwent a comprehensive consultation process.

- *Public consultation* — On 8 August 2009 a public notice in the Weekend Australian invited persons and/or bodies to make a submission on the draft document within a 30-day period. Submissions were received from 17 individuals and organisations (see below).
- *Targeted consultation* — Relevant organisations across the nation were invited to attend a targeted consultation forum on 16 September 2009. The targeted consultation forum covered key issues concerning the draft document, including the non-clinical aspects and ethical considerations. The engagement of an independent, professional facilitator (Dr Michael Smith) enabled full participation

[4] National Health and Medical Research Council. Organ and tissue donation after death for transplantation: guidelines for ethical practice for health professionals. http://www.nhmrc.gov.au/publications/synopses/_files/e75.pdf; 2007.

and active contribution from the 65 representatives of the relevant organisations (participants are listed below).

Evaluation

The consultation process outlined the need to redraft and restructure the Organ Transplantation Eligibility Guidelines and Allocation Protocols in line with the feedback generated by the written submissions and discussions at the Forum. In the time proceeding the dissemination of the draft document, there has been further review and revision, incorporating where feasible, the submission comments received during the public consultation period and the feedback obtained at the targeted consultation forum. All 20 submissions received during the public consultation period have been responded to by the Working Party with a justification as to why a submission comment has or has not contributed to the amendments made in the redrafted document.

With the assistance of the technical writers, the redrafted document has been revised in the appropriate language and style for a general and target audience. The redrafted document will undergo a further round of public consultation.

Revision

It is intended that the TSANZ clinical standing committees will meet annually to review the eligibility and allocation criteria for organ transplantation. Where required, the criteria 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.

Participants in the consultation process

Workshop participants, 19 & 20 March 2009

New South Wales

Richard Allen
Carrie Alvaro
Emily Beck
Alison Bond
Jeremy Chapman
Josette Eris
Allan Glanville
Michelle Harkess
Paul Jansz
David Joseph
Yves Kerdraon
Geoff McCaughan
Peter Macdonald
Leigh McKay
Fiona Mackie
John Males
Henry Pleass
Paul Robertson
Kellie Thomas
Deborah Verran
Trish Wills
Jenni Wright

Victoria

Peter Bergin
Michael Fink
Anne Griffiths
Winita Hardikar
Marisa Herson
Rhonda Holdsworth
Frank Ierino
Robert Jones
John Kanellis
Bron Levvey
Violet Marion
Ian Michell
Justin Negri
Alan Saunder
Greg Snell
Allan Turner
Rob Weintraub
Glen Westall

Queensland
Glenda Balderson
Scott Campbell
Tina Coco
Sharon Cull
Jonathan Fawcett
Anthony Griffin
George Javorsky

South Australia
Mark Brooke-Smith
John Chen
James Dellit
Kathy Hee
Steven Nailer
Christine Russell

Western Australia
Frank Christiansen
Anne Cowie
Lawrence Dembo
Bulang He
Ashley Irish
Gary Jeffrey
Linda Manning
Melissa Smith

Northern Territory
Lee Wood

Australian Capital Territory
Richard McCluskey
Holly Northam

New Zealand
Helen Evans
Ed Gane
Janice Langlands
Tanya McWilliams
Steve Munn
Peter Ruygrok

Submissions received – public consultation period, 8 August 2009 – 7 September 2009

Mark Brooke-Smith	SA
Anne Cahill Lambert AM	Gift of Life Inc
Gavin Carney	ACT
Anthony JF d'Apice	VIC
Luc Delriviere	Western Australian Kidney Transplant Service
Geoffrey Dobb	Organ Donation Transition Working Party, Department of Health, WA
George Javorsky and Andrew Galbraith	QLD
Vicki Jermyn	NSW
Robyn Kirwan	WA
Hemant Kulkarni	WA
Chien-Li Liew	SA
Timothy Mathew	National Consumer Council, Kidney Health Australia
Steven McTaggart	Australian and New Zealand Paediatric Nephrology Association
Julie Pavlovic	Transplant Nurses' Association
Jane Ruane	NSW
Girish Talaulikar	Renal Services, ACT Health
Kevin Yuen	Donate West, WA

Targeted consultation – participating organisations, 16 September 2009

Australia and New Zealand Dialysis and Transplant Registry
Australia and New Zealand Liver Transplant Registry
Australia and New Zealand Organ Donation Registry
Australian Association of Social Workers
Australian and New Zealand Society of Nephrology
Australian Organ and Tissue Authority
Australian College of Critical Care Nurses
Australian Heart/Lung Transplants Association
Australian Institute of Health & Welfare
Australian Red Cross Blood Service
Caring for Australians with Renal Impairment
Consumers Health Forum of Australia
Dialysis and Transplant Association of Victoria Inc
Eye Bank Association of Australia and New Zealand
HeartKids Australia
Gift of Life Inc
Hepatitis Australia
Kidney Health Australia
National Health and Medical Research Council - National Institute of Clinical Studies
National Pancreas Transplant Registry
NSW Health
NSW DonateLife
Organ Donation and Transplantation Foundation of Western Australia
Plunkett Centre for Ethics in Health Care
QLD DonateLife
Renal Resource Centre
Renal Society of Australasia
Royal Australasian College of Surgeons
Royal Australasian College of Physicians
Transplant Australia
Transplant Nurses' Association
Therapeutic Goods Administration
Thoracic Society of Australia & New Zealand
Transplantation Society of Australia & New Zealand
WA Health
Zaidee's Rainbow Foundation

D EMERGING AREA: INTESTINAL TRANSPLANTATION

Intestinal transplantation is currently an emerging therapy. At the time of writing, no intestinal transplants have been performed in Australia, although there is a designated unit at the Austin and Royal Children's Hospitals, Melbourne, with an active waiting list of children and adults.

Indications

Intestinal transplantation is a recognised treatment for patients with intestinal failure who have life-threatening complications of total parenteral nutrition (TPN). Intestinal failure is the inability to maintain adequate nutrition with an enterically administered diet and can be due to short bowel syndrome or functional causes, including motility disorders. TPN remains the gold standard for treatment of intestinal failure; the 5- and 10-year patient survival for children receiving TPN is 89% and 81%, respectively and the 5- and 10-year survival for adults receiving TPN is 78% and 75%, resectively.[1-2] However, long-term TPN can result in life-threatening complications and therefore intestinal transplantation is indicated in the following situations:[3]

- TPN-induced impending or overt liver failure, manifested by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopoenia, gastro-oesophageal varices, coagulopathy, stomal bleeding, hepatic fibrosis or cirrhosis;
- central line access failure, as evidenced by central venous thrombosis of two or more vessels, pulmonary embolism, superior vena cava syndrome or chronic venous insufficiency;
- severe sepsis, as evidenced by two or more episodes per year of systemic sepsis secondary to line infection that require hospitalisation or a single episode of line-related fungaemia, septic shock or acute respiratory distress syndrome; and
- frequent episodes of severe dehydration despite intravenous fluid supplementation in addition to TPN.

In patients for whom loss of central venous access is an indication, the referral should be made prior to the patient losing all access, as central venous access is necessary for survival during the transplant surgery, as well as for adequate postoperative care.

It is estimated that fewer than 10 patients per year in Australia would require intestinal transplantation.

Contraindications

Contraindications to intestinal transplantation include:[4]

- metastatic cancer;
- ongoing or recurrent infections that are not responding to treatment;
- significant cardiac or pulmonary conditions;
- demonstrated patient non-compliance;
- significant psychiatric or social risk;
- potential complications from immunosuppressive therapy that are unacceptable to the patient; and
- loss of central line access.

Options

The options for intestinal replacement include isolated intestine, liver plus intestine and standard and modified multivisceral transplantation, which may include any or all of liver, stomach, duodenum, pancreas, small intestine and colon.[5] The factors that determine the choice of graft include liver function and gastric motility. The type of graft is tailored to the individual patient.

Donor selection

The selection of appropriate deceased donors is critical to the success of intestinal transplantation.[6] In general, only the best donors would be considered for intestinal transplantation. The following factors are considered important in donor selection:

- age < 55 years;
- ABO identical to recipient;
- limited inotrope dose;
- stable haemodynamics;
- preferably EBV and CMV negative or matched to recipient;
- reasonable size match (donor 50–100% of recipient weight); and
- satisfactory macroscopic appearance of organs to be transplanted.

Due to a lack of size-matched organs for paediatric recipients, reduced size intestine +/– liver transplantation has been performed in some units.[7] It is not anticipated that this will occur in the Melbourne unit in the short term.

Allocation

In the initial stages of intestinal transplantation in Australia, there will a limited number of potential recipients (perhaps only one size- and ABO-matched recipient) for each suitable donor. With time, it is anticipated that transplant activity will increase and it will then be necessary to set out allocation criteria. This is likely to prioritise patients at greatest risk of waiting list death as well as those with the best post-transplant outcomes. The prioritisation system would need to balance the risk of death for patients with different risk factors for death, including liver failure, sepsis and loss of vascular access. In addition, allocation would need to take account of the competing needs of patients waiting for organs that may be transplanted with the intestine, such as liver and pancreas.

Outcome

The 4-year graft survival for intestinal transplants performed in recent years is 46%.[8] Approximately 60% of survivors have full graft function.[9]

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E CURRENTLY RECOGNISED TRANSPLANTATION UNITS

Heart transplantation units

NSW	St Vincent's Hospital
VIC	Alfred Hospital Paediatric – Royal Children's Hospital
QLD	Princes Charles Hospital
WA	Royal Perth Hospital
NZ	Auckland Public Hospital

Renal transplantation units

NSW	The Children's Hospital at Westmead
	John Hunter Hospital
	Prince of Wales Hospital
	Sydney Children's Hospital
	Royal North Shore Hospital
	Statewide Renal Services (Royal Prince Alfred Hospital)
	St George Hospital
	St Vincent's Hospital
	Westmead Hospital
VIC	The Alfred Hospital
	Austin Hospital
	Monash Medical Centre
	Royal Children's Hospital
	The Royal Melbourne Hospital
	St Vincent's Hospital
QLD	Queensland Renal Transplant Service (Princess Alexandra and Mater Children's' Hospitals)
SA	Queen Elizabeth Hospital
	Women's and Children's Hospital
WA	Princess Margaret Hospital for Children
	Royal Perth Hospital
	Sir Charles Gairdner Hospital

Lung transplantation units

NSW	St Vincent's Hospital
VIC	Alfred Hospital
QLD	Prince Charles Hospital
WA	Royal Perth Hospital

Liver transplantation units

Adult transplantation	
NSW	Royal Prince Alfred Hospital, Sydney
VIC	Austin Hospital, Melbourne
QLD	Princess Alexandra Hospital, Brisbane
SA	Flinders Medical Centre, Adelaide
WA	Charles Gairdner Hospital, Perth
NZ	Auckland City Hospital, Auckland
Paediatric transplantation	
NSW	Children's Hospital at Westmead
VIC	Royal Children's Hospital, Melbourne
QLD	Royal Children's Hospital, Brisbane
NZ	Starship Children's Hospital, Auckland

Simultaneous pancreas and kidney transplantation 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.

NSW	Australian National Pancreas Transplant Unit Westmead
VIC	Australian National Pancreas Transplant Unit Monash
NZ	New Zealand National Pancreas Transplant Unit Auckland

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 Human research Ethics Committee (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)

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)

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)

F KIDNEY ALLOCATION ALGORITHMS

National formula

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 age 17 and on dialysis for > 1 yr		+ 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			

In rare situations there may not be enough patients in a given state to be able to accept the available kidneys. Most often this occurs if the donor has a rarer blood group, such as AB. If there are not enough patients to receive the kidneys locally, a national override list is run. This list incorporates patients from across the country, to ensure that the kidneys do not go to waste.

National override list

Base score		0
Paediatric bonus	if age < 18, first dialysis before age 17 and on dialysis for > 1 yr	+ 30 000
Peak PRA > 50%		+ 1000 * (peak PRA% - 50)
Patient dialysis waiting period > 0		+ Wait in months * 100

New South Wales formula (NSW, ACT)

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 age 17 and on dialysis for > 1 yr	+ 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 age 17 and on dialysis for > 1 yr	+ 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)

Victorian formula (VIC, TAS)

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 – no score set, patients listed in urgency listing	
Base score	0
Urgency bonus when urgency index > 0	0

Queensland formula

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 Australian formula

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 – no score set, patients listed in Urgency listing	
Base score	0
Urgency bonus when urgency index > 0	0

West Australian formula

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

G DETERMINING LIVER RECIPIENT SUITABILITY

MELD and PELD scores

MELD score = 0.957 x Log_e(creatinine mg/dL) + 0.378 x Log_e(bilirubin mg/dL) + 1.120 x Log_e(INR) + 0.643

Multiply the score by 10 and round to the nearest whole number

Laboratory values of < 1.0 are set to 1.0 for the purposes of the MELD calculation

The maximum serum creatinine is 4.0 mg/dL. This includes those patients on dialysis.

PELD Score = 0.480 x Log_e(bilirubin mg/dL) + 1.857 x Log_e(INR) – 0.687 x Log_e(albumin g/dL) + 0.436 if patient is <1 year old + 0.667 if the patient has growth failure (<-2 standard deviations)

Multiply the score by 10 and round to the nearest whole number

Laboratory values of <1.0 are set to 1.0 for the purposes of the PELD calculation

See http://www.unos.org/resources/meldpeldcalculator.asp

HCC MELD

If the maximum tumour diameter is ≤ 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 > 2 cm but total tumour burden is within UCSF criteria (no tumour > 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.

King's College Hospital criteria for liver transplantation in acute liver failure

1. Paracetamol (acetaminophen)-induced liver failure:

- pH of arterial blood (after rehydration) of <7.3 or
- all three of the following critera:
  - international normalised ratio (INR) >6.5;
  - Serum creatinine >300 micromol/L; and
  - Grade III or IV encephalopathy.

2. Non-paracetamol-induced acute liver failure:

- INR > 6.5; or
- three of the following five criteria:
  - age <11 or > 40;
  - serum creatinine >300 micromol/L;
  - jaundice-to-coma time of > 7 days;
  - INR > 3.5; and
  - drug toxicity.