



**THE TRANSPLANTATION SOCIETY OF
AUSTRALIA AND NEW ZEALAND**

ORGAN TRANSPLANTATION FROM DECEASED DONORS:

**CONSENSUS STATEMENT ON
ELIGIBILITY CRITERIA AND ALLOCATION PROTOCOLS**

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Contents

INTRODUCTION	VII
PART A — ELIGIBILITY CRITERIA	1
1 Issues affecting eligibility.....	2
2 Heart recipient suitability criteria	4
2.1 Criteria for referral for assessment	4
2.1 Inclusion criteria	5
2.2 Exclusion criteria.....	5
3 Kidney recipient suitability criteria.....	8
3.1 Inclusion criteria	8
3.2 Exclusion criteria.....	8
3.3 Assessment and acceptance principles.....	9
4 Liver recipient suitability criteria.....	10
4.1 Inclusion criteria	10
4.2 Exclusion criteria.....	10
4.3 Special circumstances.....	11
5 Lung recipient suitability criteria	12
5.1 Inclusion criteria	12
5.2 Exclusion criteria.....	12
6 Pancreas and Islet	13
6.1 Criteria for referral to National Pancreas Transplant Unit	13
6.2 Inclusion criteria — solid organ pancreas	14
6.3 Exclusion criteria — solid organ pancreas	14
6.4 Inclusion criteria — pancreatic islet	14
6.6 Exclusion criteria — pancreatic islet.....	15
References	16
PART B: ALLOCATION PROTOCOLS	21
7 Issues affecting allocation of organs	22
8 General organ donor information	24
8.1 Organ donation.....	24
8.2 Assessment of the risk of disease transmission from donor to recipient.....	24
8.3 Medical history	25
8.4 Investigations.....	26
8.5 Donor risk classification.....	26
8.6 Hepatitis B testing and use of hepatitis B positive donor organs.....	27
8.6 Hepatitis C testing and use of hepatitis C positive donor organs	28
9 Donor heart allocation.....	30
9.1 Heart donor suitability criteria.....	30
9.2 Donor information required for allocation	31
9.3 Organ allocation and distribution	31
9.4 Individual patient allocation	31
10 Donor kidney allocation	33
10.1 National Organ Matching System.....	33
10.2 Allocation principles.....	33
10.3 Allocation algorithms	34

11 Donor liver allocation	36
11.1 Urgent patients.....	36
11.2 Non-urgent patients.....	36
12 Donor lung allocation	38
12.1 Lung donor suitability criteria.....	38
12.2 Donor information required for allocation	38
12.3 Organ allocation and distribution	38
12.4 Individual patient allocation.....	39
13 Donor pancreas and islet allocation	40
13.1 Pancreas donor suitability criteria	40
13.2 Donor information required for allocation	40
13.3 Organ retrieval mechanisms	41
13.4 Organ allocation and distribution	41
13.5 Individual patient allocation.....	42
References	43
APPENDICES	47
A Membership of the working party	48
B Standing Committees of TSANZ – Terms of Reference	49
C Process report	50
Participants in the consultation process.....	51
D Issues for further discussion	56
E Emerging area: Intestinal transplantation	60
F Currently recognised transplantation units	62
G Kidney allocation algorithms	64
H Determining liver recipient suitability	67

List of tables

8.1 Recommendations for transplantation based on serological testing for hepatitis B	27
8.2 Recommendations for transplantation based on serological testing for hepatitis C	29
9.1 Standard criteria for heart donation.....	30
9.2 Extended criteria (marginal) for heart donation	30
9.3 Donor information required for heart allocation	31
9.4 Donor heart — individual patient allocation criteria.....	31
11.1 Categories of patients for urgent liver transplantation	36
12.1 Suitability criteria for lung donation ¹⁻⁵	38
12.2 Donor information required for lung allocation.....	38
12.3 Donor lung — individual patient allocation criteria.....	39
13.1 Standard criteria for pancreas donation.....	40
13.2 Extended criteria for pancreas donation after cardiac death ^{3,7}	40
13.3 Donor information required for pancreas allocation	40
13.4 Donor information required for pancreatic islet allocation	41

Abbreviations and acronyms

Ab	antibody	ATCA	Australasian Transplant Coordinators Association
ACT	Australian Capital Territory	BMI	body mass index
AICD	automatic implanted cardioverter defibrillator	BSL	blood sugar level

CMV	cytomegalovirus	NOMS	National Organ Matching System
CRT	cardiac resynchronisation therapy	NSW	New South Wales
DBD	donation after brain death	NT	Northern Territory
DCD	donation after cardiac death	NYHA	New York Heart Association
EBV	Epstein Barr virus	O ₂	oxygen
ECG	electrocardiogram	PaCO ₂	partial pressure of carbon dioxide in the blood
ECMO	extracorporeal membrane oxygenator	PaO ₂	partial pressure of oxygen in the blood
FiO ₂	fractional inspired oxygen	PCR	polymerase chain reaction
GFR	glomerular filtration rate	PEEP	positive end-expiratory pressure
HAART	highly active antiretroviral therapy	PELD	paediatric end-stage liver disease
Hb	haemoglobin	PRA	panel reactive antibodies
HbA _{1c}	glycated haemoglobin	PVR	pulmonary vascular resistance
HBcAb	hepatitis B core antibody	QLD	Queensland
HBsAb	hepatitis B surface antibody	RNA	ribonucleic acid
HBsAg	hepatitis B surface antigen	RTAC	Renal Transplant Advisory Committee
HCCAb	hepatitis C core antibody	SA	South Australia
HCC	hepatocellular carcinoma	TAH	total artificial heart
HIV	human immunodeficiency virus	TAS	Tasmania
HLA	human leucocyte antigen	TGA	Therapeutic Goods Administration
HLT _x	heart-lung transplant	TPG	transpulmonary gradient
HREC	Human Research Ethics Committee	TPHA	syphilis antibody
HTLV	human T-lymphotrophic virus	TPN	total parenteral nutrition
ICU	intensive care unit	TSANZ	Transplantation Society of Australia and New Zealand
IgG	immunoglobulin G	UCSF	University of California San Francisco
LFT	lung function test	VAD	ventricular assist device
LVEF	left ventricular ejection fraction	VIC	Victoria
MELD	Model for End-Stage Liver Disease	VRE	vancomycin-resistant enterococcus
MRSA	methicillin-resistant staph aureus	WA	Western Australia
NAT	nucleic acid testing		
NHMRC	National Health and Medical Research Council		

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 and organs for transplantation.

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 some malignancies including post-transplant lymphoma.

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 it to the circulatory system. The technique may be used to support an impaired cardiac and 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 leucocyte 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.

PaCO₂: Partial pressure of carbon dioxide in the blood. Critical in regulating breathing levels and maintaining body acid base balance.

Panel reactive antibody (PRA): is a blood test that is routinely performed on patients waiting for organ transplants and measures anti-human antibodies in the blood. The PRA score is given as a percentage and can be from 0% to 99%. The higher a patient's PRA, the more difficult it is to find a compatible organ for them, because of the risk of immediate antibody-mediated rejection of the transplanted organ.

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 failure. 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. Strict medical and legal criteria apply before a living donation can proceed and, in Australia, eye and tissue donation and transplantation is regulated by the Therapeutic Goods Administration. The focus of this document is on solid organ 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 (other than kidneys) is offered primarily to patients who have end-stage organ disease, who have exhausted all alternative treatment options. Furthermore, transplants are primarily offered to patients 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 – A World's Best Practice Approach to Organ and Tissue Donation for Transplantation and one of its key initiatives 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 the TSANZ 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 criteria 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 justly, 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 take into account the following ethically irrelevant factors:

- race; religion;
- gender;
- marital status;
- sexual orientation;
- social status;
- capacity to pay;
- the need for transplant arising out of past behaviour;

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

² NHMRC (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>.

location of residence; and
age (except where age may affect the outcome).

Decisions regarding eligibility and allocation will 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 Part A. The assessment process requires referred 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 obligation of transplant teams to exercise responsible stewardship of the community's healthcare resources (including donated organs). 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](http://www.health.gov.au/internet/main/publishing.nsf/Content/B5AC5303C8932F30CA25747A000BF6A4/$File/ORGAN%20FACT%20SHEET.pdf). Accessed 30 July 2009. 2008.

Part A — Eligibility criteria

1 ISSUES AFFECTING ELIGIBILITY

The scarcity of donor organs means that clear-cut eligibility criteria are required to ensure a just and equitable system for the delivery of this therapy. Determining eligibility in an environment where need outweighs availability 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 a multidisciplinary transplant team that includes a credentialed transplant surgeon; 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 team 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 F.

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: The fact that an individual may require a transplant due to lifestyle choices they have made in the past is ethically irrelevant. However, ongoing substance abuse, including excessive alcohol consumption, cigarette smoking and illicit drug taking, are generally considered contraindications to transplantation. These lifestyle factors can result in poorer outcomes.³⁻⁹

Inability to comply with complex medical therapy: For example chronic cognitive or neuropsychiatric deficits in the absence of a carer capable of taking on this role.

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.

Any patient who has been assessed as being unsuitable for transplantation has the right to a second opinion. Patients who wish to seek a second opinion should be referred to another Australian transplant unit. Medical professionals should ensure that medical records and the results of all relevant investigations are made available to facilitate any such second opinion. The development of alternative appeal mechanisms is outside the scope of this project. The Australian Organ and Tissue

Authority is responsible for the implementation of this document. It is envisaged that audit processes will be developed by the Authority to monitor adherence to the eligibility criteria and allocation protocols across Australia to ensure consistency and transparency of clinical practice.

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 need and availability, 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 advanced 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

Most patients referred for heart transplantation have chronic (long-standing) heart failure. Before referral for heart transplantation, patients 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 prognosis⁷ 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.

Acute heart failure

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

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.

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. A decision on whether or not to refer patients with a history of chronic infection for heart transplant assessment needs to be individualised and generally should only be made in consultation with the infectious disease specialist and any other specialists caring for the patient.

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 hypoalbuminaemia²⁷ 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 The lifestyle benefits of transplantation mean that even some patients who would be unlikely to significantly increase their life expectancy with a transplant might like to have one if there were enough organs available.

Unfortunately, the number of kidneys available for transplantation from deceased donors is far short of the number of patients who might benefit from a kidney transplant.^{5,6} 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.⁵⁻⁷ 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.⁷

The severe shortage of kidneys means that not everybody who might benefit from, and who might want a kidney transplant can get one. Because of this, preference is given to patients who are likely to achieve a greater survival with their new kidney. The benefit to the community of this scarce and valuable resource is lessened if too many kidneys are transplanted into patients whose life expectancy is significantly less than the expected survival of the transplanted kidney.

The figure of an anticipated 80%, 5-year survival for transplant candidates will result in some patients who might benefit from a kidney transplant being deemed ineligible for listing. Some of these patients may still be able to be transplanted with a kidney from a live donor. Only listing patients with an 80% or better chance of surviving 5 years, will still result in many more patients being listed, than we are currently able to transplant. Setting such a target means that all renal transplant units will be using the same benchmark for assessing patients. It also allows for the audit of results, and the ability to modify the assessment process in the future if it is found that some units are being more stringent or more lax than the suggested level.

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%.⁸

3.1 Inclusion criteria

Inclusion criteria for kidney transplantation are:

- end-stage kidney failure requiring dialysis;
- anticipated low perioperative mortality; and
- 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 as follows.

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

Cardiovascular disease — Substantial, uncorrectable cardiovascular disease would be an absolute exclusion. Lesser levels of disease would potentially contribute to a lower anticipated 5-year survival, and hence would be a relative consideration.^{15,16}

[#] It is recognised that the use of a post-transplant survival estimate as a criterion for transplant eligibility is a contentious issue. See Appendix D for further discussion

Diabetes mellitus – Uncomplicated diabetes mellitus is not a contra-indication to transplantation. The presence of diabetes should lead to detailed assessment of potential vascular complications that would potentially contribute to a lower anticipated 5-year survival, and hence would be a relative consideration.^{17,18}

Infection — Uncontrolled infection is a contraindication to transplantation.

Malignancy — Active malignancies other than non-melanoma skin cancers remain an absolute contraindication to kidney 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 kidney transplant assessment needs to be individualised and generally should only be made in consultation with the oncologist caring for the patient.

Inability to comply with complex medical therapy — The ability to correctly follow a treatment plan, particularly with respect to anti-rejection medications is an important predictor of a successful outcome after renal transplantation, and as such is a requirement for renal transplant listing. Every effort should be made to assist patients and their carers to optimise their adherence to therapy.

Other medical conditions — Patients with renal failure can have any number of comorbid medical conditions that can affect the chances of a successful outcome. Others include cardiac failure, chronic airways disease, cirrhosis of the liver, peripheral vascular disease and cerebrovascular disease. The impact of these conditions needs to be considered on a case-by-case basis.

Age — 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.⁷

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

Patients who are being considered for a second or subsequent kidney transplant should be assessed according to the same requirements as candidates for their first kidney transplant.

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 H);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 H);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 Hospital criteria (see Appendix H).

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}

inadequate or absent social support is a relative contraindication to liver transplantation (because of an increased risk of non-adherence);^{9,10} and

severe neurocognitive impairment and/or developmental delay in a potential paediatric candidate.

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) guidelines¹¹ 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.

Patients who meet these criteria might be considered for combined transplantation. The decision to list a patient for a combined liver/kidney transplant should be taken by both the liver and renal transplant teams.

Patients will be considered for re-transplantation if they fulfil criteria, as above, for either acute or chronic liver disease with an expected post-transplant survival rate exceeding 50% at 5 years.

5 LUNG RECIPIENT SUITABILITY CRITERIA

Lung transplantation is a highly effective treatment for advanced lung disease.^{1,2} Generally a 60% 5-year and 40% 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 this document.

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}

It is also possible that, even after active listing for transplantation, an individual later develops a new complication or becomes too unwell to successfully undertake transplantation. In this circumstance, an individual may then be delisted temporarily (if the situation can be resolved) or permanently (if the condition is unresolvable). Intensive interventions such as mechanical ventilation or extracorporeal membrane oxygenation (ECMO) may be used to provide a short-term 'bridge' to transplantation, but are complex therapies that may be associated with just such a deterioration, and ultimately transplantation may not be feasible.

Recent international guidelines were formulated with Australian input, and Australian and New Zealand units follow these recommendations.^{4,5}

5.1 Inclusion criteria

Inclusion criteria for lung transplantation are:

- respiratory failure despite optimal medical, interventional and surgical treatment; and/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^{4,5}):

- 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, however 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 Re-transplantation may be an appropriate consideration if an individual deteriorates post-transplant and re-qualifies within the inclusion and exclusion criteria.

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 F). 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 must 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 age⁸ 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 1 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 – not aspirin) that cannot be safely ceased (in the short term) 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);
- ongoing cigarette smoking;
- 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); 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 (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/1.73m²;
- serum creatinine < 130 mol/L;
- 24-hr urine protein estimation < 300 mg/day;
- weight < 75 kg;
- the patient has read and signed the islet-specific informed consent form (as islet transplantation is currently being performed as part of a clinical study);
- 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;
- creatinine clearance < 75 mL/min/1.73 m²;
- serum creatinine > 130 mol/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, pimozone, 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 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 vii).

Transplant units should use donated organs in a way that balances 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 deterioration of health without transplant therapy, especially if patient survival is immediately threatened by that deterioration;

- 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

The successful transplantation of organs from any given deceased donor requires coordination of the logistics involved with:

- retrieval of the donor organs;

- identifying and ensuring the timely availability of all recipients; and

- all involved transplant units arranging and performing the transplant procedures.

Organ retrieval mechanism

Each jurisdiction has processes in place to identify teams for both multi-organ abdominal procurement and thoracic viscera procurement as dictated by the requirements for any given deceased donor with respect to local or interstate acceptance/allocation of the organs.

Organs are deemed transplantable at the time of organ procurement by procurement surgeons in consultation with transplant surgeons. This may require at times adjunctive information ie results of biopsies [which may not be available until post organ procurement]. Arrangements for the transport of organs are made according to the organ type and whether organs are for local use or interstate use.

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 (the ischaemic time) 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, and vice versa, if there is no suitable recipient in New Zealand. The rotation of offers to those units is held by the New Zealand Donor Coordinators.

Allocation of hearts and livers is dictated first by urgency and then defaults to the local unit and finally to the interstate rotation.

For lungs and non-urgent hearts and livers, distribution is organised and offers are made through the State DonateLife™ 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 acute liver failure intubated in the intensive care unit, 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 while on support). 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, 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 either using the 'brain function criterion' (donation after brain death [DBD]) or 'irreversible cessation of the circulation criterion' (donation after cardiac death [DCD], also known as non-heart-beating donation [NHBD]). DBD remains the preferred donation pathway because it results in the retrieval of more organs of better quality. Further details regarding the identification and management of donation after cardiac death are provided in a separate document, *National Protocol for Donation after Cardiac Death*, to be issued by the Australian Organ and Tissue 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 Assessment of the risk of disease transmission from donor to recipient

Organ transplantation is associated with a risk of transmission of some infectious diseases including HIV, hepatitis B, hepatitis C and other blood-borne viruses.¹⁻³ There is also a risk of transmission of malignancy.^{1,3} While it is possible to reduce the risks of transmission of infectious and other diseases it is not possible to completely eliminate the risk. The risk of transmission of disease must be balanced against the need to perform some transplants urgently. The medical urgency of transplantation for some potential recipients may mean that transplanting organs from donors with increased risk is contemplated at times. In addition, where transplantation is life saving, an increased risk of disease transmission may be regarded as acceptable to the recipient. Conversely, where transplantation is not life saving but aims to improve the quality of the recipient's life, a greater margin of safety is appropriate. Nonetheless, no absolute guarantee can be given that transmission of infection (of a known or unknown agent) or other disease to recipients will never occur, as there are limited time frames for organ donor assessment and the risk of transmission has to be balanced against the medical need of recipients.

Chronic viral infections that are transmissible via organ transplantation include those that are highly prevalent (cytomegalovirus [CMV], Epstein Barr virus [EBV], BK/polyoma, herpes simplex virus, varicella), those that occur in a minority (hepatitis B, hepatitis C, HIV, human herpes virus 6 and 8) and those that occur rarely (human T-lymphotrophic virus [HTLV] I and II, Creutzfeldt-Jakob disease) among deceased donors in Australia and New Zealand. Viral infections may be associated with acute life-threatening disease, chronic damage to the transplanted or other organs, increased risk of opportunistic bacterial and fungal infections or malignancy.¹

8.3 Medical history

The standardised Australasian Transplant Coordinators Association (ATCA) Confidential Donor Referral Form, which contains a past and current medical history and lifestyle questionnaire, will be completed for all donors.

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;
 - sexual contact with a high-risk partner, which may include male-to-male sex, sexual activity with a male who is bisexual, sex with a male or female sex worker;
 - sex industry worker;
 - time in prison;
- history of risk factors for the transmission of Creutzfeldt-Jakob disease:
 - family history of early dementia;
 - use of pituitary hormone extract;
 - notification of treatment with pituitary hormone extract;
- history of diabetes, hypertension or other cardiovascular disease; 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. Specific attention must be paid to:

- clinical, laboratory or investigative indicators of transmissible neoplastic disease;⁴
- immediate past and current cardiovascular status;
- medication given to the donor;
- transfusion of blood or blood replacement products (haemodilution may result in false-negative serological test results);
- all surgical interventions undertaken during the admission; and
- active 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 and other cancers known to have been fully eradicated from the donor may be considered after careful risk/benefit analysis);
- active HIV infection; and
- uncontrolled infection (donor sepsis).

8.4 Investigations

Mandatory investigations

- Blood group for ABO and Rhesus.
- HIV type 1 antibody.
- HIV type 2 antibody.
- Hepatitis B surface antibody (HBsAb).
- Hepatitis B surface antigen (HBsAg).
- Hepatitis B core antibody (HBcAb).
- Hepatitis C antibody (HCcAb).

Recommended investigations

- CMV IgG antibody.
- EBV capsid IgG antibody.
- HTLV I and II antibody, especially for donors from high-risk groups.
- Syphilis antibody (TPHA).
- Nucleic acid testing (NAT) for hepatitis C and HIV using polymerase chain reaction (PCR) assays — This allows recent infection with hepatitis C or HIV to be detected and therefore is more sensitive than performing serology alone. NAT assays significantly reduce the 'window period' compared to antibody testing,⁵ however a negative NAT result does not completely eliminate the possibility of recent or previous infection. NAT is desirable for donors in increased-risk categories either from their medical history or laboratory tests.⁶
- Beta human chronic gonadotrophin hormone in female of child-bearing age dying from unexplained intracerebral haemorrhage.
- A postmortem examination.

8.5 Donor risk classification

Donors who are known to have HBV and/or HCV infection

Where there is a requirement to detect a co-infection in a donor who is already known to be infected with hepatitis B and/or hepatitis C, the specimen should have both serology and NAT testing performed (co-infection can cause a significant reduction in the level of one or other genomes).

The request form should request assessment for HIV/hepatitis C co-infections using serology and NAT and indicate that the patient is known to be infected with hepatitis B/hepatitis C.

Donors with identified risk factors/behaviours or donors whose risk factors cannot be reliably assessed

Decisions about the suitability of organ retrieval from these donors requires serology +/- NAT.

Where the donor's risk behaviours can be reliably determined and there is no indication that risk behaviours have occurred within the last **6 months** then serology alone is acceptable.

Where the donor's risk behaviours can be reliably determined and there is no indication that risk behaviours have occurred within the last **2 months** then serology and NAT are required **prospectively**.

Where there is concern regarding the donor's risk behaviour **and** it cannot be reliably determined **or** the behaviour may have occurred within the last **2 months** then, irrespective of the serology and NAT (which should be done **prospectively**), organ donation should not proceed unless there is a recipient whose death is imminent without immediate transplantation and the transplant unit **and** the

potential recipient (or the recipient's next-of-kin or "person responsible" if the recipient is not competent) accepts the risk of transmission of infection.

Depending on laboratory timetables for NAT, it may be necessary to request urgent out-of-hours testing of these specimens to obtain a prospective result.

Donors with no identified risk factors/ behaviours

Decisions about organ retrieval from these donors are based on the results of serology.

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

Hepatitis B serology testing

Serological testing of donors for hepatitis B — hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb) and hepatitis B core antibody (HBcAb) — may reveal different patterns of response as indicated in Table 8.1.

Table 8.1 Recommendations for transplantation based on serological testing for hepatitis B

Serological result	Donor status	Recommendations for transplantation
HBsAg+ve (HBcAb should be +ve)	Active Infection	Not suitable for transplantation except in emergency situations Discussion with hepatologist mandatory
HBsAb+ve HBsAg–ve HBcAb–ve	Vaccinated	Suitable for transplantation
HBsAb–ve HBsAg–ve HBcAb–ve	No exposure and not vaccinated	Suitable for transplantation
HBsAb–ve HbsAg–ve HBcAb+ve or HBsAb+ve HbsAg–ve HBcAb+ve	Hepatitis B virus exposure	Suitable for transplantation recipient at risk of hepatitis B reactivation Discussion with hepatologist recommended

A positive result for HBcAb alone may indicate:

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

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

Liver transplantation: the risk of hepatitis B transmission by transplantation of livers from donors who are HBsAg+ve is universal and reactivation of hepatitis B from HBcAb+ve HBsAg–ve donors is high.^{7–13} Recent data demonstrate that transmission of infection can be prevented by use of lamivudine monotherapy in the recipient of a HBcAb+ve donor liver.^{14–16}

Other solid organ transplantation: There are fewer data on transmission of infection from HBcAb+ve donors after transplantation of other solid organs or tissue.^{7,17–19} Published studies suggest that the risk of development of clinical hepatitis in transplant recipients of organs from HBcAb+ve donors is low.

Tissue transplantation: The data available on the use of heart valves from HBsAg+ve donors in both immune and non-immune patients showed hepatitis B infection in 1 of 31 individuals and prophylaxis after transplantation is recommended.²⁰

Recommendations

All potential donors must be tested for HBsAg and HbCAb

Use of organs from HBsAg+ve donors should be considered only in emergency situations and only after discussion with a hepatologist or infectious diseases physician. Organs from HbCAb+ve donors may in certain situations be used with consent and the risk of hepatitis B reactivation can be managed with long-term anti-hepatitis B antiviral therapy (see below).

Where there is uncertainty of the significance of hepatitis B serology or if there is consideration of use of HbCAb+ve or HBsAg+ve donors, discussion with a hepatologist or infectious diseases physician is recommended.

Liver organ donor with HBsAg+ve or HbCAb+ve serology:

HBsAg+ve 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+ve HBsAg–ve donors should be considered for transplantation, provided informed consent is obtained and anti-hepatitis B antiviral therapy is used in the recipient.

Non-liver vascularised organ donors with HBsAg+ve or HbCAb+ve serology:

HBsAg+ve donors must not be used for HBsAg–ve recipients.

HBsAg–ve but HbCAb+ve donors can be used but the recipient should ideally be immune to and/or vaccinated against 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.

The non-urgent and non-life-threatening nature of the indications for tissue transplantation require that all HBsAg+ve donors represent a potential risk for transmission of hepatitis B and their tissues must not be used. Donors who are HBsAg–ve but HbCAb+ve represent an unknown risk for the transmission. If tissues from HbCAb+ve donors are considered, prophylactic treatment of the recipient should be considered and informed consent must be obtained.

8.6 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+ve subjects are currently infected. It has been estimated that approximately 50% of hepatitis C donor organs are hepatitis C ribonucleic acid (RNA)+ve assessed by PCR (positive NAT assay).^{21,22} It is only hepatitis C PCR+ve donors who have been documented to transmit infection²³ and up to 100% of these donors transmit infection to recipients.²¹

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.^{24,25} There are few data as yet on the natural history of HCV infection after lung transplantation.²⁶

A Hepatitis C Positive Register exists to allow transparent and equitable allocation of kidneys from hepatitis C positive donors to hepatitis C RNA+ve 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+ve and Ab–ve recipients.²⁷ There are data to suggest that subjects with higher pre-transplant and post-transplant viral loads have poorer outcomes^{28,29} and earlier data indicated that patients who require

liver transplant with genotype 1b also have poorer outcomes,²⁷ but this has not been supported in all studies.

Some data suggest that recipients of hepatitis C positive livers do not have a worse outcome.^{30,31} 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.³²

Conclusions from the current data

Organs from hepatitis C Ab+ve donors should not be used for hepatitis C Ab–ve 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+ve donors may be used for non-liver hepatitis C Ab+ve recipients who are RNA+ve following PCR testing: Hence the PCR status of recipients should be known. The use of hepatitis C Ab+ve donor organs for hepatitis C Ab+ve PCR+ve recipients should not be dismissed. 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+ve donors may be used for hepatitis C RNA+ve (PCR+ve) 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+ve donors, 50% of whom may be RNA–ve (PCR–ve), will affect outcomes is not available. 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.

Recommendations

All potential donors must be tested for hepatitis C Ab and hepatitis C RNA (NAT testing)

Table 8.2 Recommendations for transplantation based on serological testing for hepatitis C

Serological and RNA (PCR) Result	Donor/Recipient Status	Recommendations for transplantation
Hepatitis C Ab+ve donor and hepatitis C Ab–ve recipient	Donor hepatitis C infection* Recipient not infected or exposed to hepatitis C	Not suitable for transplantation
Hepatitis C Ab+ve donor and hepatitis C Ab+ve RNA–ve (PCR–ve) recipient	Donor hepatitis C infection* Recipient not currently infected with HCV	Not suitable for transplantation
<i>Non-Liver Transplant:</i>		
Hepatitis C Ab+ve donor and hepatitis C Ab+ve RNA+ve (PCR+ve) recipient	Donor hepatitis C Infection* Recipient hepatitis C infection	May be considered following specific informed consent
<i>Liver Transplant:</i>		
Hepatitis C Ab+ve donor and hepatitis C Ab+ve RNA+ve (PCR+ve) recipient	Donor hepatitis C infection* Recipient hepatitis C infection	Should be considered following specific informed consent

* Probable active hepatitis C infection. While some individuals who are Hepatitis C Ab+ve and RNA–ve (PCR–ve) may have cleared hepatitis C virus it is also possible they have fluctuating low level viraemia and hence should be regarded as having active infection.

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 is controversial 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 g/kg/min or equivalent

Table 9.2 Extended criteria (marginal) for heart donation

Donor age 50–60 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 (absolute risk of death at 1 year increased from 12 to 18%). The relative risk of death at 1 year post-transplantation rises to 80% at a donor age of 60 years (absolute risk of death at 1 year of 22%). ² There is limited data on post-transplant outcomes for cardiac donors over the age of 60 years. A one year mortality rate in excess of 40% has been reported and for this reason donors over the age of 60 years are considered unsuitable for heart transplantation. ³
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 ³ (absolute risk of death at 1 year increased from 12 to 16%)
Donor requiring high-dose inotropic support	Noradrenaline > 0.2 g/kg/min or equivalent ⁴
Donor graft dysfunction on echo	Left ventricular ejection fraction (LVEF) < 50%, major wall motion abnormality. ⁵
Donor comorbidities	eg donor hepatitis B or C positive or high risk behaviour. ^{5,6}

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, HBsAb, HBcAb, hepatitis C Ab, CMV, EBV serology
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 30 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 30-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 ⁷
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 and 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 ⁸

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 coordination with other donor retrieval teams, transport of surgical teams and donor organs, type of heart transplant operation (orthotopic, heterotopic or domino) and number of transplants to be performed (usually heart and lung transplants are performed simultaneously in separate operating theatres) and the availability of intensive care unit (ICU) beds.

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 antibodies against other people's tissue types; and
- whether the patient is a child (paediatric patients get priority; see explanation below).

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 primarily tries to find suitable kidneys for patients who have a very high level of human leucocyte antigen [HLA]-antibodies (antibodies against other people's tissues) and hence derive the greatest benefit from a well-matched kidney. The system also maintains an approximate 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 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 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 (PRA over 50%) and only 0, 1 or 2 HLA mismatches with the donor. It also allocates kidneys to patients who have a perfect tissue (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 G.

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:

- 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.¹¹

Kidneys from donors after cardiac death (DCD) will be treated the same as kidneys from donors after brain death. This is to try to ensure that patients with a lot of antibodies against other people, have the best chance of receiving a compatible kidney.

Simultaneous kidney and pancreas transplantation offers the best clinical outcomes for patients with type 1 diabetes mellitus.¹² 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. When such patients are listed, allocation to them is mandatory.
Status 2a	<p>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 H. This includes patients who have acute liver failure because of vascular thrombosis in a liver allograft.</p> <p>In addition, this category includes paediatric candidates with severe acute or chronic liver disease who have deteriorated and are in a paediatric intensive care unit. When such patients are listed, allocation to them is usual but not mandatory. It is subject to discussion between the directors (or delegates) of donor and recipient state (or NZ) liver transplant centres.</p>
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 H) score exceeds the standard MELD score of other patients on the list of the same ABO blood group;

the quality of the donor liver¹⁻³ — 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.

23 June 2011 Vs 1.1

So called 'marginal' livers will be used and allocated based on the above algorithm. No specific category of patient is excluded from the use of such marginal organs.

12 DONOR LUNG ALLOCATION

12.1 Lung donor suitability criteria

Table 12.1 Suitability criteria for lung donation¹⁻⁵

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 Fiberoptic 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 30 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 30-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). Although it is known that a variety of factors may manifest as apparent donor lung 'quality' (and be measured as oxygenation, chest X-ray abnormalities and bronchoscopy findings), there is no specific or universally recognised extended donor category.

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} A decision regarding the configuration of single, double or lobar transplantation will reflect these logistic issues, donor quality and the pre-determined specific requirement of any potential individual recipient. Donor lungs are allocated by the accepting lung transplant unit 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 O₂ requirement
- Low-flow O₂ 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 Medical research Council (MRC) grade
- significant fall in lung function parameters
- significant fall in PaO₂
- significant rise in partial pressure of carbon dioxide in the blood (PaCO₂)
- significant fall in 6-minute walk test distance
- need for escalation in level of support as above
- time course of progression of radiological changes
- development of symptomatic pulmonary hypertension
- development of refractory right heart failure

** 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.^{4,5}

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 ischaemic 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	Inotrope 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

Lymphocytotoxic 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	Inotrope 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

Organ allocation and distribution currently follow patterns that have been established over several years based on referral patterns of organ recipients and geographical considerations regarding retrieval teams and acceptable ischaemic times. This process is being reviewed on an ongoing basis. 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:

Mike Catton

Patrick Coghlan

Michael Fink

Malynda Flarey

Andrew Marich

Geoffrey McCaughan

Steven McTaggart and the Members of the TSANZ Paediatric Standing Committee

Helen Opdam

William Rawlinson

Aviva Rosenfeld

Nicholas Shackel

William Silvester

Michael Smith

Bernadette Tobin

Deborah Verran

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 recipient eligibility, donor organ retrieval, allocation and standards of practice.

- Will formulate standards of practice that are audited and reviewed regularly.

- Will oversee and regularly review the eligibility criteria and 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 and community 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 TSANZ and the Australasian 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 National Reform Agenda – A World's Best Practice Approach to Organ and Tissue Donation for Transplantation, TSANZ obtained funding from the Australian Department of Health and Ageing (subsequently transferred to the Authority) to enhance the role of its Standing Committees to convene a multidisciplinary group of transplantation clinicians, health-care professionals, and consumer representatives to develop nationally uniform eligibility criteria 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 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 Standing Committees convened for a 2-day consensus development workshop on 19–20 March 2009. The enhanced role of the TSANZ Standing Committees made it possible for a multidisciplinary group across all state 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 target audience of the eligibility criteria and allocation protocols for organ transplantation is health professionals with the document written in a way that it is accessible to the wider community. The criteria have been developed and revised according to consensus on 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 as outlined below.

The first stage of the consultation process took place on 8 August 2009 with a public notice in the *Weekend Australian* inviting persons and/or bodies to make a submission on the draft document within a 30-day period; written submissions were received from 18 individuals and organisations (see below). As part of the consultation process, relevant organisations and individuals across the nation were invited to attend a targeted consultation forum scheduled 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

⁴ NHMRC (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>; 2007.

facilitator (Michael Smith) enabled full participation and active contribution from the 65 representatives of the relevant organisations.

The second stage of the consultation process took place on 27 March 2010 with a public notice in the *Weekend Australian* inviting persons and/or bodies to make a submission on the revised document within the period specified in the notice; written submissions were received from 24 individuals and organisations. Invitations were sent to the relevant organisations to attend a targeted consultation forum scheduled on 30 April 2010; 57 representatives attended this forum facilitated by Michael Smith. The targeted consultation forum addressed the issues identified during the first stage of the consultation process.

Revision

The first stage of the consultation process outlined the need to redraft and restructure the document in line with the feedback generated by the written submissions and discussions at the targeted consultation forum. With the assistance of the technical writers, the document was revised in the appropriate language and style for the target audience: health professionals and the wider community. The second stage of the consultation process allowed for further revision and refinement, and the inclusion of issues raised during the consultation period that were unable to be resolved prior to the final version of the document.

The Working Party has considered and responded to all the feedback received during the consultation period and amended the eligibility criteria and allocation protocols for organ transplantation accordingly.

It is intended that the TSANZ Standing Committees will be funded to meet regularly to review the eligibility criteria and allocation protocols for organ transplantation. It is also expected that an annual review forum will be funded which will allow regular community, consumer and other stakeholder input into the eligibility criteria and allocation protocols. Where required, the criteria will be revised if evidence emerges that supports improvements in clinical practice and outcomes. The National Reform Agenda – A World's Best Practice Approach to Organ and Tissue Donation for Transplantation has targeted funding aimed at increasing deceased organ donations in Australia. Any increase in the number of organs available will have an impact on the number of transplantations occurring, and may result in further revision of the eligibility criteria for listing and allocation protocols.

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 — first 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	West Australian Kidney Transplant Service
Geoffrey Dobb	Organ Donation Transition Working Party, Department of Health, Western Australia
Sue Huckson and Matthew Sammels	National Institute of Clinical Studies, National Health and Medical Research Council
George Javorsky and Andrew Galbraith	QLD
Vicki Jermyn	NSW
Robyn Kiwan	WA
Hemant Kulkarni	WA
Chien-Li Liew	SA
Timothy Mathew	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	DonateWest, WA

Submissions received — second public consultation period, 27 March 2010 – 23 April 2010

Peter Bergin	VIC
Anne Cahill Lambert, AM	Gift of Life Inc.
Scott Campbell	Renal Transplant Advisory Committee
Gavin Carney	ACT
Alan Cass	NSW
Katy Coppin	State Donor Nurse Consultants NSW
Luc Delriviere	West Australian Kidney Transplant Service
Geoffrey Dobb and Roderick McRae	WA
Sue Huckson	National Institute of Clinical Studies, National Health and Medical Research Council
Margaret Klass	Nationally Funded Centres Reference Group
Graham Kyd	Transplant Services, Royal Prince Alfred Hospital
Guy Maddern	Royal Australasian College of Surgeons
Stephen McDonald	SA
Stella McGinn	NSW
Steven McTaggart	TSANZ Paediatric Standing Committee
David Parker	Kidney Health Australia
Julie Pavlovic	Transplant Nurses' Association
Andrew Pesce	Australian Medical Association
Bruce Pussell	NSW
Girish Talaulikar	Renal Services, ACT Health
Christopher Thomas	Transplant Australia
Deborah Verran	NSW Transplant Advisory Committee
Rowan Walker	Caring for Australasians with Renal Impairment Guidelines
Jenni Wright	National Organ Matching Service

Targeted consultation forums — invited organisations, 16 September 2009 and 30 April 2010

ACT Health
Australasian College for Emergency Medicine
Australasian Donor Awareness Programme
Australasian Faculty of Public Health Medicine
Australasian Tissue and Biotherapeutics Forum
Australasian Transplant Coordinators Association
Australia and New Zealand Cardiothoracic Organ Transplant Registry

Australia and New Zealand Dialysis and Transplant Registry

Australia and New Zealand Liver Transplant Registry

Australia and New Zealand Organ Donation Registry

Australian and New Zealand Institute of Health, Law and Ethics

Australian and New Zealand Society of Nephrology

Australian and New Zealand Intensive Care Society

Australian Association of Social Workers

Australian Bone Marrow Donor Registry

Australian College of Critical Care Nurses

Australian Corneal Graft Registry

Australian Council on Healthcare Standards

Australian Federation of AIDS Organisations

Australian Health ethics Committee

Australian Heart/Lung Transplants Association

Australian Institute of Health and Welfare

Australian Medical Association

Australian Organ and Tissue Authority

Australian Red Cross Blood Service

Caring for Australians with Renal Impairment

Centre for Values, Ethics and the Law in Medicine

Consumer Representatives

Consumers Health Forum of Australia Inc.

Cooperative Research Centre for Aboriginal Health

David Hookes Foundation

Department of Health and Families of the Northern Territory

Department of Health and Human Services Tasmania

Dialysis and Transplant Association of Victoria Inc

Donatelife - ACT

DonateLife - NSW

DonateLife - NT

DonateLife - QLD

DonateLife - SA

DonateLife - TAS

DonateLife - VIC

DonateLife - WA

Eurobodalla Renal Support Group and Organ Donor Awareness

Eye Bank Association of Australia and New Zealand

Gift of Life Inc.

HeartKids Australia

D ISSUES FOR FURTHER DISCUSSION

There are issues that have been raised during the development process that are unable to be resolved before the final version of this document is released. These issues include:

- governance issues;
- using likelihood of survival as an eligibility criterion;
- alternate listing;
- logistics in allocation and equal right of access for rural and regional patients;
- the use of prospective HLA matching in the allocation of donor kidneys;
- pancreas organ allocation to units based on waiting list activity, auditing of pancreas organ allocation and waiting times between units;
- re-transplantation;
- appeals mechanisms; and
- NHMRC approval.

The following discussion summarises some of the perspectives around these issues and is included to illustrate that these issues have been considered, but are yet to be resolved. It is recognised by the working party that this document is establishing for the first time a national consensus on the eligibility criteria and the allocation protocols for organ transplantation. This document is not the end of the process but part of a longer term project. It is envisaged that the Australian Organ and Tissue Authority will continue to support the TSANZ Standing Committees to meet regularly to review the criteria outlined in this document, as well as an annual public consultation forum to enable ongoing consumer and community input. It is anticipated that these meetings will inform future revisions of the document.

Governance

The respective roles of TSANZ, the Australian Organ and Tissue Authority and consumers in the process of developing and maintaining the eligibility criteria and allocation protocols for organ transplantation has been raised as an issue that requires clarity and further discussion. The Consensus Statement has been developed by the TSANZ Standing Committees with input from a wide range of stakeholders. The document is the property of TSANZ, however it is expected that the Australian Organ and Tissue Authority and state jurisdictions will be responsible for the implementation of the eligibility criteria and allocation protocols that have been articulated in the document. It is also envisaged that transparent audit mechanisms will be developed by the Authority in collaboration with TSANZ and that annual audit reports will be published to ensure adherence to the agreed eligibility criteria and allocation protocols.

Using likelihood of survival as an eligibility criterion

In the kidney and heart sections, the likelihood of survival is listed as an eligibility criterion. For a recipient to be suitable for heart transplantation, this is expressed as "a life expectancy of at least 10 years after transplantation with a reasonable prospect of returning to an active lifestyle after transplantation". The average life expectancy after heart transplantation in Australia and New Zealand is currently 14 years. For a recipient to be suitable for kidney transplantation this is expressed "as a reasonable postoperative life expectancy, defined as an 80% likelihood of surviving for at least 5 years after transplantation". At present, kidney transplant recipients in Australia and New Zealand have a 5-year survival rate of close to 90%. The liver section lists the following in the 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 current 5-year survival rate for liver transplant recipients in Australia and New Zealand is more than 80%.

Ultimately, the "likelihood of survival" is essentially a utilitarian concept aimed at addressing the large gap that currently exists between need and availability. Donated organs from deceased donors are a community resource and there is a community expectation that these scarce resources will be used in

a way that provides the greatest improvement in life expectancy and quality of life for the recipient of that organ.

The main argument for the use of this criterion is that setting such a target means that all transplant units will be using the same benchmark for assessing patients. It also allows for the audit of results, and the ability to modify the assessment process in the future if it is found that some units are being more stringent or more lax than the suggested level. Only listing patients who meet this eligibility criterion will still result in many more patients being listed than we are currently able to transplant. A counter argument is that there is no guarantee that a patient assessed as having a reasonable likelihood of surviving postoperatively for 5 years or longer will not die within days or weeks. Current results suggest, however, that transplant teams are already applying similar criteria and that they are very skilled at discriminating between those patients who will do well after transplantation and those who will not. Further research on the ability of medical professionals to predict post-transplant outcomes is desirable. Consideration should be given to the questions as to why the survival threshold differs between organs and why it has been applied to some organs and not others. One difference is that patients with kidney failure can survive for years on dialysis, whereas patients with severe heart, liver or lung failure die without transplantation. It is acknowledged that there are barriers to good transplant outcomes that may be beyond an individual's control, particularly for socially disadvantaged groups. The provision of equitable health care for disadvantaged groups is a complex issue and one that spans the entire spectrum of health care delivery of which organ transplantation is a small part. The challenge for society is to improve all aspects of health care delivery to disadvantaged groups so that they can derive the full benefits of organ transplantation.

Alternate listing

In an attempt to increase the availability of organ transplantation, particularly for heart and kidney transplantation, several transplant units, mainly in the United States have implemented an "alternate list" policy. This policy involves the utilisation of donor organs that are judged to be of too poor quality for transplantation into patients on the unit's transplant waiting list. These organs are then offered to patients on the alternate waiting list. Patients accepted onto the alternate list have generally been older (> 65 years) with co-morbidities (eg complicated diabetes mellitus, other systemic illness) that would exclude them from acceptance onto a standard transplant waiting list. Morbidity and mortality outcomes for "alternate list" patients who undergo organ transplantation are significantly higher than for "standard list" patients, but overall outcomes are generally regarded as superior to the outcomes of these patients had they continued with medical therapy. Judged in this way, "alternate listing" appears to be a clinically effective strategy, however the policy creates significant ethical conflicts particularly with regard to equity and its implementation will increase the demand on ICU and overall hospital resources.

Logistics in allocation and equal right of access

It is recognised that all patients, irrespective of their location, should have the same chance of receiving a transplant based upon clinical need. As outlined in this document, logistical considerations sometimes factor into the allocation process, a fact that at first may seem at odds with this principle. As it is impossible to predict exactly when an organ may become available, there are circumstances that arise from time to time that result in factors other than clinical factors being used in the allocation process. This may include workforce issues such as surgeon or ICU availability, or other logistical considerations beyond the control of the transplant unit, such as weather preventing transport.

Organ transplantation is a complex medical therapy, and medical professionals in the field of transplantation require a range of technical competencies to ensure a successful outcome. Consideration should be given to the resource issues within the transplant units, the need to ensure that there is access to well-qualified and experienced medical practitioners at the time the organ becomes available, and that the hospital resources such as ICU beds are available. Consideration should also be given to the need for organs to be transplanted within a specific time frame from when the organ is procured to ensure a successful outcome; this time period or targeted ischaemic time differs from organ

to organ and ranges from less than 6 hours for heart transplantation to less than 24 hours for kidney transplantation. As such, if weather, flight delays or an accident affects road travel and prevents a patient from arriving at the transplant centre within the necessary time period required for a successful transplant, these factors will have a bearing on who is transplanted on that day.

Most patients waiting for transplantation wish to be managed at home if they are well enough, however there is a need for patients to reside in a location that is not so remote to allow them to be transferred to the transplant unit on the day a donor organ becomes available. Consideration should be given to the resources required to ensure arrangements are made for the recipient to be accommodated in closer proximity to the hospital if required. Consideration should also be given to the need to audit allocation decisions to identify how often and which specific logistical issues impact on allocation decisions so that appropriate measures can be implemented to minimise the impact of logistical factors on allocation decisions. This may require additional resources for the transplant units to ensure equity of access.

The use of prospective HLA matching in the allocation of donor kidneys

During the consultation process it was noted that HLA matching was used in the allocation of kidneys but not for other organs. The additional survival benefits of HLA matching are well established. The importance of HLA matching in the current era of more effective immunosuppression is less than in earlier eras, but in Australia the difference in graft survival for a very well matched kidney versus a very poorly matched kidney is in the order of 5–10%. Furthermore there are subsets of patients, including those who have previously been transplanted and those with a lot of anti-HLA antibodies, whose outcomes are dramatically better if they are able to achieve a close HLA match.

Results from transplantation of other organs indicate that excellent long-term graft and patient survival can be achieved without prospective HLA matching. In addition, with increased utilisation of marginal donors other factors such as ischaemic time may emerge as important determinants of long-term kidney graft survival. Despite a superficial appearance of fairness and equity the application of prospective HLA matching effectively discriminates in favour of those with the common HLA antigens of the dominant racial / ethnic group(s) and against groups with less common HLA antigens. It is critical that if higher risk patients are to continue to be transplanted, that the system endeavours to find them well-matched kidneys where possible. There has been a gradual move over time to decrease the reliance on HLA matching in the renal allocation algorithms. It needs to be recognised that complete elimination of matching would result in lesser outcomes for those individuals for whom it would have been possible to find an excellent match.

Pancreas organ allocation to units based on waiting list activity; Auditing of pancreas organ allocation and waiting times between units

As combined pancreas and kidney organ allocation is performed as a "priority" prior to kidney allocation, there is a need for improved and ongoing comparisons of outcomes between:

those waiting for; and

those receiving – combined pancreas kidney transplant versus subgroups for kidney only transplant.

Further consideration as to the pancreas organ allocation processes may arise from these audit processes.

Re-transplantation

As there is such a significant gap between the need for organ transplantation and the availability of donor organs, concern has been raised about the process of re-transplantation; that is a patient being transplanted for a second or subsequent time. A view has been expressed that these patients have already had their turn, and that the donated organ should be provided to another person on the waiting list who has never been transplanted.

The question that needs to be considered is should there be a blanket policy that no patient should receive two organ transplants regardless of the circumstances? If so, what are the implications for those patients who received transplants in childhood or even young adulthood if they experience organ

failure 15 or 20 years post transplant? What are the implications for a patient who accepts a marginal organ, and derives the expected, less than average graft survival from that organ? What are the consequences for wastage of marginal organs if patients decline to accept any marginal organs because they will only ever receive one organ?

The overriding ethical principle articulated by ethicists is that the decision to list someone for transplantation should be based on medical need. For some organ transplants (eg heart), when the transplanted organ has failed shortly after the transplant procedure, the outcomes for re-transplantation are very poor. These patients are not suitable candidates for re-transplantation. If however, a patient has had a successful transplant many years prior, and that donor organ is now failing or has failed, the results of re-transplantation are much better and these patients may meet the eligibility requirements outlined in this document. If there is a strong likelihood of a similarly good outcome compared with a patient who has never been transplanted before, should the fact that they have had a transplant previously preclude them from transplantation or should re-transplantation be considered based upon the individual patient's circumstances?

Appeals mechanisms

As with any medical therapy, patients who have been assessed as unsuitable for organ transplantation have the right to seek a second opinion. Medical professionals should ensure that medical records and the results of tests and other investigations are made available to facilitate any such second opinion. The Australian Organ and Tissue Authority and state jurisdictions are responsible for the implementation of this document, and as such the development of formal appeal mechanisms are outside the scope of this project and sits separately from the role of the TSANZ in this process. It is envisaged that audit processes will be developed to monitor the allocation decisions made across Australia to ensure consistency and transparency of clinical practice.

NHMRC approval

The need to submit the Eligibility Criteria and Allocation Protocols via the NHMRC approval processes has been raised. Given the breadth of the information to be covered, the timeframe allowed for the project and based on the advice sought from the Australian Organ and Tissue Authority, it was determined that a consensus opinion document was the most appropriate way forward at this stage. This document was developed broadly utilising the framework outlined in the NHMRC Standards and Procedures for Externally Developed Guidelines, however the requirements of the full NHMRC approval processes would necessitate a significantly longer time period and resources than this project allowed. This document is viewed as a starting point. It may progress into the development of NHMRC guidelines and be submitted through the NHMRC approval processes. The merits of this approach should be considered in the future.

E 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%, respectively.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, thrombocytopenia, 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 be 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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F 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 East Coast Renal Transplant Service (Prince of Wales Hospital and Sydney Children's Hospital) John Hunter Hospital Royal North Shore Hospital Statewide Renal Services (Royal Prince Alfred 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	Royal Adelaide 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
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VIC	Austin Hospital, Melbourne
QLD	Princess Alexandra Hospital, Brisbane
SA	Flinders Medical Centre, Adelaide
WA	Charles Gairdner Hospital, Perth
NZ	Auckland City Hospital, Auckland
<i>Paediatric transplantation</i>	
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)
SA The Royal Adelaide Hospital	(HREC-approved protocol)
VIC St Vincent's 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 Royal Adelaide Hospital/IMVS	(HREC-approved protocol)
VIC St Vincent's Islet Laboratory	(HREC-approved protocol)

G 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 HLA-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 HLA-A or HLA-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)

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

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

State HLA

Base score	if no Mismatches at HLA-DR	50 000 000
	For each mismatch at HLA-A	- 1 000 000
	For each mismatch at HLA-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)	
<p>If Victorian patients do not fit the criteria for national allocation, Victorian NOMS Program assigns a starting score of 40,000,000. Patients lose 20,000,000 for each HLA- B or HLA-DR mismatch. Therefore if a Victorian patient has 2 HLA-B and/or HLA-DR mismatches their score reduces to zero and any added scores are for months on dialysis. i.e. waiting time only applies. However waiting time also applies in the matching list. For example if a patient has one donor HLA-DR mismatch and has been waiting 60 months for a graft, the score will be 20,000,060.</p>	
State HLA	
Base score	40 000 000
For each mismatch at HLA-B	- 20 000 000
For each mismatch at HLA-DR	- 20 000 000
If total mismatches at HLA-B and HLA-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	
<p>The Queensland NOMS programme primarily determines who will receive kidneys by HLA matching, or by the time a patient has been on dialysis. Firstly all patients on the waiting list, who are of the correct blood, group are matched against the donor. If there are any very well matched patients (no more than 2 mismatches out of 6) then the NOMS programme allocates it to the patients with the best match. This happens about 50% of the time. The other 50% of the time, there is nobody on the waiting list who is well matched with the donor. In these cases NOMS ignores the HLA matching altogether, and produces a list of ABO blood group compatible patients, in order of who has been on dialysis longest. A patient's renal physician should be able to give the patient an approximate idea of how long it will take them to be allocated an organ for their blood group, and whether there are any special circumstances that might make it harder than usual for them to get a kidney.</p>	
State HLA	
Base score	50 000 000
For each mismatch at HLA-A	- 1 000 000
For each mismatch at HLA-B	- 1 000 000
For each mismatch at HLA-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

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

State HLA	
Base score	30 000 000
For each mismatch at HLA-A	- 10 000 000
For each mismatch at HLA-B	- 10 000 000
For each mismatch at HLA-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

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

State HLA	
Base score	40 000 000
For each mismatch at HLA-A	- 3 000 000
For each mismatch at HLA-B	- 3 000 000
For each mismatch at HLA-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

H DETERMINING LIVER RECIPIENT SUITABILITY

MELD and PELD scores

$$\text{MELD score} = 0.957 \times \text{Log}_e(\text{creatinine mg/dL}) + 0.378 \times \text{Log}_e(\text{bilirubin mg/dL}) + 1.120 \times \text{Log}_e(\text{INR}) + 0.643$$

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.

$$\text{PELD Score} = 0.480 \times \text{Log}_e(\text{bilirubin mg/dL}) + 1.857 \times \text{Log}_e(\text{INR}) - 0.687 \times \text{Log}_e(\text{albumin g/dL}) + 0.436 \text{ if patient is } < 1 \text{ year old} + 0.667 \text{ if the patient has growth failure (} < -2 \text{ standard deviations)}$$

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 criteria:

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 bilirubin > 300 micromol/L;

jaundice-to-coma time of > 7 days;

INR > 3.5 ; and

drug toxicity.