Organ Transplantation From Deceased Donors: Eligibility & Allocation Protocols

Summary
This policy provides the framework for the implementation in NSW of the Transplantation Society of Australia and New Zealand: Organ Transplantation from Deceased Donors: A Consensus Statement on Eligibility Criteria and Allocation Protocols. The Consensus Statement Protocols relate to the referral, assessment and listing of patients awaiting solid organ transplantation in NSW and the allocation of deceased donor organs to patients on transplantation waiting lists within Australia.

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Audience
Admin;Directors of Clinical Governance;Clinical Operations;Nursing;Surgery & Transplantation

Secretary, NSW Health
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ORGAN TRANSPLANTATION FROM DECEASED DONORS:
Consensus Statement Eligibility Criteria and Allocation Protocols

PURPOSE
This policy provides the framework for implementation in New South Wales (NSW) of
the Transplantation Society of Australia and New Zealand Organ Transplantation from
Deceased Donors: A Consensus Statement On Eligibility Criteria And Allocation
Protocols (the Consensus Statement). Consensus Statement Protocols relate to patient
referral, assessment and listing and allocation of deceased donor organs.

The Consensus Statement is available at:

Guidelines for implementation of Consensus Statement Protocols and compliance with
the audit requirements prescribed in the Consensus Statement are at Attachment 1.

Procedures for the review of eligibility assessment processes are at Attachment 2.

MANDATORY REQUIREMENTS
Consensus Statement Protocols must be used by recognised Transplant Units for
assessment of patients for eligibility for deceased donor organ transplantation.

Tissue typing for transplantation will only be conducted if it is authorised by a
recognised Transplant Unit.

IMPLEMENTATION
Roles and responsibilities of the NSW Department of Health:
• Provide advice and assistance for the implementation of this policy.
• Monitor and evaluate the health system implementation of the Consensus
  Statement Protocols and Guidelines.

Roles and responsibilities of Chief Executives:
• Ensure that personnel involved in the management of patients requiring listing for
  transplantation are aware of the requirements of this policy directive.
• Assign responsibility, personnel and resources to implement the Consensus
  Statement Protocols and Guidelines within their Local Health Network.

Roles and responsibilities of health service executives responsible for
clinical operations and governance:
• Ensure successful implementation of the Consensus Statement Protocols and
  the Guidelines.
• Monitor and evaluate the implementation of the Consensus Statement Protocols
  and the Guidelines across their services
• Ensure the Guidelines are incorporated into the local orientation program for
  relevant clinical staff.
Roles and responsibilities of recognised Transplant Units:

- Implementation of and adherence to the Consensus Statement Protocols for assessment, review, referral and pre-transplantation management of patients.
- Ensure that assessments and decisions regarding eligibility for transplantation are documented in a format that allows for an audit of records to determine compliance with the requirements of this policy.
- Ensure that records include demographic data (e.g. age; gender; post-code; identification of Aboriginal or Torres Strait Islander origin information [as per PD2005_547 Principles For Recording Aboriginal And Torres Strait Islander Origin Information Of Patients And Clients] and data regarding the renal unit from which the patient was referred for transplant.
- Conduct an annual audit of implementation of the Consensus Statement Protocols eligibility and allocation criteria.
- Submit a report of the audit to the relevant TSANZ Standing Committee and the NSW Transplant Advisory Committee which includes data on:
  - the number of documented patient assessments undertaken by the Transplant Unit using the TSANZ organ specific eligibility criteria;
  - the number of patients documented as eligible for acceptance onto the NSW transplantation waiting list;
  - the number of patients documented as ineligible for acceptance to NSW transplantation waiting list;
  - the number of referrals to another recognised Transplant Unit of patients seeking a second opinion; and
  - the number of patients who request a review of the eligibility assessment process after a second assessment found them to be ineligible for transplantation.

Roles and responsibilities of referring clinicians:

- Referring clinicians are responsible for ensuring their practices are consistent with the Consensus Statement Protocols and the Guidelines, including the options for review of the assessment process for patients deemed ineligible for transplant.

REVISION HISTORY

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<tr>
<th>Version</th>
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<td>May 2011 (PD2011_026)</td>
<td>Deputy Director-General Population Health</td>
<td>New policy</td>
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ATTACHMENTS

1. Guidelines for the implementation of the Consensus Statement on Organ Transplantation from Deceased Donors: Eligibility Criteria and Allocation Protocols
2. Transplantation Eligibility Review Panel.
Guidelines for the implementation of the Consensus Statement on Organ Transplantation from Deceased Donors: Eligibility Criteria and Allocation Protocols

Background
Organ transplantation is a highly effective treatment for advanced organ failure. Currently the number of patients who may benefit from transplantation is higher than the number of organs donated from deceased donors each year in Australia. This limitation requires that robust criteria and protocols are developed and applied to both the listing of patients for transplantation and to the allocation of deceased donor organs to patients on the waiting list.

The Transplantation Society of Australia and New Zealand has recently published Organ Transplantation from Deceased Donors: A Consensus Statement On Eligibility Criteria And Allocation Protocols (the Consensus Statement Protocols). This document provides guidance to clinicians and the public on nationally consistent eligibility and allocation criteria.

These Guidelines support implementation of the Consensus Statement Protocols and compliance with audit requirements.

Management of patients assessed as eligible for listing for transplantation
Transplant Units should consider all options for pre-transplantation management to occur at the local level. Patient safety is paramount, therefore management at the local level will be dependent on case complexity; and the availability of appropriate local resources, including specialist staff and technological capacity.

Clear lines of responsibility should be identified for the Transplant Unit and the referring clinician. Correspondence to referring physicians regarding a listed patient should include investigations considered essential and desirable; the time frame within which the results of investigations are required; and other guidance for ongoing care. If appropriate, other specialist resources which may be available to the referring clinician should be identified by the Transplant Unit.

The agreed care plan should include a review date in addition to a clinical summary of the patient.

A communication mechanism should be developed between the patient, the referring physician and the Transplant Unit; and the name, email and telephone number of the Transplantation Case Manager should be provided.

To minimise travel-related burden, the Transplant Unit team should consider the use of technology such as video conferencing where possible for the review of patients from rural and regional settings.
Listed patients may be removed from the transplant list if their condition improves or deteriorates to the point where they no longer meet the eligibility criteria for transplantation.

**Management of patients assessed as ineligible for listing for transplantation**

Patients who are assessed as ineligible for transplantation have the right to know the reasons for the clinical decision.

The patient should be informed of the decision by the Transplant Unit and documentation should be provided to the referring physician which includes the reasons for ineligibility; options for seeking a second opinion and a review of the assessment process following second opinion that the patient is ineligible for transplantation; and guidance for ongoing care.

Transplant Units should develop standardised documents for providing information to ineligible patients and their referring physicians.

Kidney Patients assessed as ineligible for deceased donor organ transplant may be considered for live donor transplantation in accordance with the provisions of PD2011_007 *Kidney Donation – Living (including Directed and Non-Directed Donation)*.

If a patient who is seeking eligibility for the NSW Kidney Required List requests a second opinion, then the referring physician should offer the option of referral to another appropriate NSW Renal Transplant Unit. Where the patient lives in a NSW border area, referral to a Transplant Unit in an adjacent State or Territory may present the best option.

For all other solid organs, NSW Transplant Units should establish formal referral networks with interstate Transplant Units for patients seeking a second opinion.

To avoid unnecessary expense and duplication of effort, relevant test results should be provided to the Transplant Unit from which the second opinion is sought.

**Mechanisms for review of eligibility assessment processes**

The NSW Transplant Advisory Committee (TAC) will convene the Transplantation Eligibility Review Panel (TERP) on a case by case basis to review assessment processes for patients who are assessed as ineligible for listing for transplant. The terms of reference and membership for the TERP are set out in Attachment 2.

**Compliance Audit**

Transplant Units are required to undertake an annual audit of records and report the outcomes to the relevant TSANZ Standing Committee and the NSW Transplant Advisory Committee.

To facilitate the conduct of the audit and preparation of the report, Transplant Units should ensure that records for each patient include sufficient detail regarding application of the organ specific eligibility criteria; correspondence to the referring physician.
regarding the outcome of the assessment process; the date of acceptance to the waiting list; and the date of entry to waiting list.

Adequate records should also be maintained regarding patient and referring physician requests for second opinions and a review of the assessment process where 2 transplant units have assessed the patient as ineligible for transplantation.

**Auditing of Allocation Criteria**

The NSW Organ and Tissue Donation Service conducts an audit of the allocation of kidneys every 6 months. This audit is reported to the Renal Transplant Advisory Committee and the NSW Transplant Advisory Committee.

All solid organ Transplant Units should also conduct an annual audit of records of allocation and provide a report to the relevant TSANZ Standing Committee and the NSW Transplant Advisory Committee. The audit report should include the number of solid organs allocated and consistency with the Consensus Statement organ specific allocation criteria.
The Transplantation Eligibility Review Panel

The Transplantation Eligibility Review Panel (TERP) will operate under the auspice of the NSW Transplant Advisory Committee.

The role of the TERP is to review the process for assessment of eligibility for listing for transplant for patients who, on the basis of a second opinion, have been assessed as ineligible.

The TERP has no role in reviewing patient eligibility for listing.

Terms of Reference:
  1. To determine whether the TSANZ Consensus Statement general and organ specific criteria were applied in determining a patient’s eligibility for listing for transplant.
  2. To determine whether all relevant factors to assessment of a patient’s eligibility for listing for transplant were considered.
  3. To determine whether the assessment process was appropriately documented.
  4. To report on reviews of the processes applied to determine eligibility to NSW Health and to the TSANZ Council.

The Panel will be convened as required.

Membership of the Transplantation Eligibility Review Panel

The Chair:
The Chair of the NSW Transplant Advisory Committee (or their delegate) will chair TERP.

Subject Matter Experts
The TAC will establish a list of subject matter experts in each of the organ specific transplantation fields who agree to be called upon by the Chair when required. Subject matter experts may be recruited from other jurisdictions.

The TAC will ensure that there are sufficient subject matter experts available to ensure that it is possible to convene a Panel which has members who are independent of the transplant units which assessed the patient who has requested the review.

Convening a Panel
The Chair will convene a Panel on a case by case basis. A Panel will have a minimum of 3 and a maximum of 5 members and should include a person with expertise in the organ-specific discipline to which the case relates and a person with expertise in assessing procedural matters such as a Patient Representative or a Health Service Manager.
Conflicts of interest
All members of the Panel, including the Chair, must be recruited from Transplant Units which have not been involved in assessment of the patient who has requested the review.

Secretariat services:
The Chair of TAC will determine secretariat arrangements on a case by case basis.

Process:
- An application for review by TERP will only be accepted in relation to a patient who has been assessed as ineligible for transplantation by 2 Transplant Units.
- Applications for review must be made in writing by the patient and their referring physician to the Chair of the NSW TAC.
- The Chair of the TAC must ensure that a Panel is convened as soon as possible and no later than 4 weeks of receiving a written application. In recognition that in certain cases a delay may have particularly detrimental consequences for a patient consideration should be given to an expedited review process.
- Applications for review must include a report regarding the referral of the patient for assessment for transplantation; and written consent from the patient for release of all relevant documentation and records to the TERP by the Transplant Units which assessed the patient.
- Where TERP finds that the assessment process for an individual patient is either not appropriately documented; and/or did not include application of the eligibility criteria set out in the Consensus Statement; and/or did not include consideration of all relevant factors; and/or included consideration of irrelevant factors, it may recommend that the patient be reassessed.
- The outcome of the review and the reasons for the decision of the panel will be conveyed in writing by the Chair to the patient, their referring physician; the Transplant Units which assessed the patient; and the TAC and reported within a month. This correspondence will be conveyed within 4 weeks of the conclusion of the review for non-urgent cases.
- The patient may choose to be reassessed by a Transplant Unit which was not involved in either of the previous assessments.
- The Chair of TAC will include a summary of TERP reviews of the process of assessment of eligibility and the outcomes in the TAC annual report to the NSW Department of Health; and to the TSANZ Council.