Policy

Examination of Potential Donor Organs in the Marginal Donor

NSWHP_PD_008

1. Purpose

1.1 This policy describes the process by which NSW Health Pathology anatomical pathologists examine potential donor organs from marginal/extended criteria donors to assist decision-making on suitability for transplantation.

2. Background

2.1 The NSW Transplant Advisory Committee requested NSW Health Pathology develop a policy for examining potential donor organs in the marginal/extended criteria donor to assist decision-making on the suitability for transplantation.

2.2 These donors may have comorbidities that may affect the donor's suitability, for example, hypertension, vascular disease or diabetes. Potential donors requiring a biopsy are a minority of the donor population. For kidney donors, information from a renal biopsy may assist the transplant team to decide whether to accept or reject the kidney/s or whether both kidneys are transplanted to a single recipient. The final decision rests with the transplant team rather than the pathologist, as other factors are also important.

3. Scope

3.1 This policy is mandatory and applies to all anatomical pathologists in NSW Health Pathology.

4. Definitions

Marginal Donor/Extended Criteria Donor: The criteria for acceptance of donor organs varies depending on the organ and is subject to ongoing revision. It is generally based on donor age and the presence of comorbidities.

5. Policy Statement

5.1 Assessment of Potential Donor Organs

The assessment of potential donor organs occurs before the organ has been transplanted and must include:

5.1.1 Pathology Request Form

a) A valid pathology request form must be submitted with the biopsy.

b) This should include the kidney laterality, donor sex, date of birth and some basic relevant clinical information, for example, history of hypertension, diabetes or smoking.

c) The requesting doctor and 'copy to' recipients for a final report must be included on the request form.

Approver: Executive Director, Strategy & Transformation, Version Number: V2.0, Publication Date: 23/06/2020 This document is subject to change and a printed copy may not be up to date. The current version is only available online in the **NSWHP Policy Library**

5.1.2 Donor Anonymity

a) Donor anonymity must be preserved by labelling request forms and biopsies with the Electronic Donor Record (EDR) Number and not the donor's name.

b) If the biopsy is not labelled with the EDR Number, an amended request form must be submitted.

c) No identifying information should be entered with the accession in the Laboratory Information System (LIS).

d) This process must not delay the commencement of the biopsy tissue processing.

5.1.3 Transplant Team Medical Staff Member Contact Details

a) The name and phone number of the medical staff member on the transplant team, who will be making the final decision on the use of the donated organ, must be available on the request form provided to the anatomical pathologist examining the tissue.

5.1.4 Site Where Biopsy Examination is to Take Place

The department that routinely provides the anatomical pathology service to the facility where the organ retrieval is taking place, must accept prime responsibility for organising pathological examination without delay. This may be via:

a) The usual in-hours urgent pathology specimen arrangements routinely available in the department, or

b) Through the hospital anatomical pathology service's usual after-hours roster system, should the biopsy be required outside the normal operating hours of the laboratory, or

c) If the retrieval is taking place in a centre without an on-site anatomical pathology service or after-hours service, the biopsy must be forwarded to the nearest pathology laboratory within the NSW Health Pathology network where the anatomical pathology services are available. These arrangements should be formalised so that problems of transport and acceptance are avoided.

d) The local anatomical pathology department should be notified in advance of the biopsy being taken to allow necessary planning.

5.1.5 Biopsy Sampling and Method

The biopsy processing method shall be at the discretion of the pathologist, taking into account the urgency of the examination, and taken in conjunction with the request from the medical suitability advisor. However:

a) For kidney and liver donations, the preference is for a core biopsy as this is more likely to be representative than a subcapsular wedge which may overestimate fibrosis.

b) The preferred method is that the biopsy is processed for three hour rapid paraffin sections. For kidneys this is usually 20 sections cut and 4 stained H and E only.

Frozen section may be used in appropriate circumstances such as wedge biopsies, for example, to exclude malignancy.

5.1.6 Reporting Requirements for Histopathological Examination

The essential histological features required for the evaluation of biopsies from deceased kidney and liver donors are as follows:

a) Potential Kidney Allografts Reporting Requirements

i. The number of glomeruli visible in the biopsy sections - record both total number and number of sclerosed glomeruli,
ii. The extent of interstitial fibrosis as an estimated percentage of cortical sample,
iii. The presence or absence of arteriolar changes, plus a comment on arterial pathology, if present,
iv. The presence or absence of inflammation, and
v. The presence or absence of tubular damage.

b) Potential Liver Allografts Reporting Requirements

i. The percentage of hepatocytes which contain large fat vacuoles (macrovesicular steatosis),
ii. The presence or absence of fibrosis,
iii. The presence or absence of inflammation - record both portal inflammation and lobular inflammation, and
iv. The presence or absence of hepatocyte damage, that is, acidophil bodies and/or necrosis.

c) Additional Commentary

i. Record any other significant pathological findings, for example, incidental neoplasia, granulomas, etc, found in the donor biopsy.

5.1.7 Distribution of Final Histopathology Report

a) At the conclusion of the assessment, an urgent interim report will be provided to the Transplant Team Medical Officer.

b) The final histopathology report will be issued within the usual laboratory reporting timeframe.

6. Roles and Responsibilities

6.1 The department that routinely provides the anatomical pathology service to the facility where the organ retrieval is taking place, must accept prime responsibility for organising pathological examination without delay.

6.2 The anatomical pathologist will make the assessment of the histological changes present in organs from marginal/extended criteria donors in accordance with section 5 of this policy.

6.3 The transplant team will make the final decision whether to transplant an organ.

6.4 A network procedure may be required to support the mandatory requirements in this procedure.

7. Legal and Policy Framework

Human Tissue Act 1983
http://www.austlii.edu.au/au/legis/nsw/consol_act/hta1983160/

Transplantation Society of Australia and New Zealand *Organ Transplantation from Deceased Donors: A Consensus Statement On Eligibility Criteria And Allocation Protocols*
http://www.tsanz.com.au/organallocationprotocols/index.asp

NSW Health Guideline GL2016_008 *Management of the Adult Brain Dead Potential Organ and Tissue Donor*
http://www0.health.nsw.gov.au/policies/gl/2016/GL2016_008.html

NSW Health Policy Directive PD2012_042 *Aboriginal and Torres Strait Islander Origin-Recording of Information of Patients and Clients*
http://www0.health.nsw.gov.au/policies/pd/2012/PD2012_042.html

NSW Health Policy Directive PD 2013_ 001 *Deceased Organ and Tissue Donation-Consent and Other Procedural Requirements*
http://www0.health.nsw.gov.au/policies/pd/2013/PD2013_001.html

NSW Health Policy Directive PD2010_067 *Organ Donation & Transplantation – Kidney Transplant Program Hep C Register & Hep C positive donors*
http://www0.health.nsw.gov.au/policies/pd/2010/PD2010_067.html

NSW Health Policy Directive PD2013_029 *Organ Donation and Transplantation – Managing Risks of HIV, HCV and HBV*
www0.health.nsw.gov.au/policies/pd/2013/pdf/PD2013_029.pdf

NSW Health Policy Directive PD2011_026 *Organ Transplantation From Deceased Donors: Eligibility & Allocation Protocols*
http://www0.health.nsw.gov.au/policies/pd/2011/PD2011_026.html

8. Review

This document will be reviewed by16/06/2022.

9. Risk

Risk Statement	If delays occur due to a lack of clarity in relation to the roles and responsibilities for assessing donor organs, the consequences could result in suboptimal clinical outcomes.
Risk Category	Clinical Care and Patient Safety

10. Further Information

For further information, please contact:

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11. Version History

The approval and amendment history for this document must be listed in the following table:

Version No	Effective Date	Approved By	Approval Date	Risk Rating	Sections Modified
1.0 Click here to see Rescinded – Examination of	31/05/16	NSWHP ELT	31/05/16	High	New Policy

potential donor organs in marginal doners – Version 1					
2.0	23/06/20	Executive Director, Strategy & Transformation	17/06/20	High	Re-templated and extended without further changes