Organ Donation and Transplantation - Managing Risks of Transmission of HIV, HCV and HBV

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Functional Sub group  Corporate Administration - Governance
Clinical/ Patient Services - Human Tissue
Clinical/ Patient Services - Infectious diseases
Population Health - Communicable Diseases

Summary  The policy directive provides a process by which clinicians can identify organ donors who are at increased risk of HIV, HBV or HCV infection, conduct appropriate and timely diagnostic testing and consult where necessary to identify circumstances where an organ that may be infectious may be transplanted and circumstances where transplantation is contraindicated. The policy directive also gives guidance with respect to informed consent from recipients with respect to HIV, HBV or HCV risk from solid organ transplantation.


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Audience  LHD Admin, clinical, nursing, critical care, ED’s, organ donation staff, transplant units/surgery.

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Policy Manual  Patient Matters

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
PURPOSE

The objectives of this policy directive are to provide a process by which clinicians can identify organ donors who are at increased risk of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV) infection (referred to hereafter as “increased risk donors”), conduct appropriate and timely diagnostic testing and consult where necessary to identify circumstances where an organ that may transmit infection may be transplanted and also circumstances where transplantation may be relatively contraindicated because of infection risk.

The policy directive also gives guidance with respect to informed consent from recipients with respect to HIV, HBV or HCV risk from solid organ transplantation.

MANDATORY REQUIREMENTS

All organ donors in NSW must be assessed for evidence of risk or risk behaviour for blood borne virus infection (BBV) prior to retrieval of organs and tissues for transplantation according to the criteria outlined in the attached document.

All organ donors in NSW must have the following serological testing prior to retrieval and transplantation of organs.

- Antibody to Human Immunodeficiency Virus, Type 1 (anti-HIV-1 Ab);
- Antibody to Human Immunodeficiency Virus, Type 2 (anti-HIV-2 Ab);\(^1\)
- Hepatitis B surface antigen (HBsAg);
- Hepatitis B core antibody (anti HBC Ab);
- Hepatitis B surface antibody (anti HBsAb);
- Antibody to Hepatitis C (anti-HCV Ab)

Donors with evidence of risk, potential risk behaviour, or where there is no medical history available must also have the results of Nucleic Acid Testing (NAT) returned prior to transplantation of organs. (Note that some donors with no evidence of risk have been diagnosed with infection, although nearly all have been identified on antibody testing).

There is a requirement in law to inform potential recipients of all material risks that acceptance or non acceptance of a particular organ might cause. Transplant physicians are responsible for ensuring that recipients give a valid consent to accepting a particular organ immediately prior to transplantation.

Post transplant infection surveillance must be undertaken by Transplant Units within NSW, and all unanticipated transplant associated infections reported immediately to the NSW Organ and Tissue Donation Service in order to facilitate testing and review of other patients receiving organs from the same donor.

\(^1\) Note that the combined HIV antibody / antigen test is acceptable.
Laboratories will also notify positive test results of scheduled medical conditions to the local Public Health Unit as appropriate.

All facilities involved in the assessment and/or transplantation of deceased donor organs must have appropriately documented procedures consistent with the attached guide.

**IMPLEMENTATION**

**Chief Executives of LHDs are responsible for ensuring that:**

- All staff are made aware of their obligations in relation to this Policy Directive.
- Documented procedures are in place to support the Policy Directive. All procedures must be consistent with the steps outlined in this guide.

**The State Medical Director of the Organ and Tissue Donation Service (OTDS) is responsible for:**

- ensuring that written procedures for the assessment and testing of deceased donors for BBV are available for all relevant personnel. All procedures must be consistent with the steps outlined in this guide.

**DonateLife Network staff based in NSW health facilities:**

- Are required to assess donor risk and arrange for appropriate testing for BBV and other infections prior to organ retrieval. Appropriate documentation of all steps outlined in the attached guide is required.

**On call Medical Consultant for the OTDS:**

- Will make the decision to proceed to retrieval of organs. Advice of the on call consultant of the donor testing laboratory or their delegate is available to the on call Medical Consultant to assist in this decision making.

**Transplantation Physicians:**

- Are responsible for accepting organs for transplantation in consultation with the recipient. Potential recipients must give a valid consent to acceptance of any organ which may be potentially infected prior to transplantation consistent with the steps outlined in this guide.

**Transplantation Unit Directors:**

- Are responsible for ensuring that post transplant infection surveillance is undertaken consistent with the steps outlined in this guide.
- Must ensure that unanticipated transplant associated infections are reported appropriately according to the attached procedures. This also includes immediate notification to the OTDS.
REVISION HISTORY

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<td>September 2013</td>
<td>Deputy Director General, Population and Public Health</td>
<td>Procedures substantially reviewed and reformatted. Flow charts amalgamated.</td>
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1 BACKGROUND

1.1 About this document

Organ transplantation is associated with a risk of transmission of some infectious diseases including HIV, HBV and HCV and other blood borne viruses (BBV). It is an absolute necessity to reduce the risk of transmission of these infections. However, it is not possible to completely eliminate this risk, and it is important to balance this risk against the life-saving, and life enhancing benefits of organ transplantation.

Some transplants need to be performed urgently in order to save specific patients’ lives, and there is a need to optimally use this scare resource. For example, where organ transplantation is life saving, a higher risk of infectious disease transmission may be acceptable to the recipient. Conversely, where transplantation aims to improve the quality of the recipient’s life, a greater margin of safety may be appropriate. However, the patient must have the opportunity to consent to such risk at a time when their underlying condition does not adversely affect their ability to make decisions.

This policy directive seeks to:

- Assist in identification of organ donors in NSW who are at increased risk of HIV, HBV or HCV infection through appropriate and timely diagnostic testing and consultation;
- Assist in decisions to allocate NSW donor organs infected by HIV, HBV or HCV; and
- Provide advice in relation to consent requirements for potential recipients and surveillance of transplant-associated BBV infections.

The policy directive does not apply to:

- Living donors;
- Tissue transplantation, blood or blood products, haemopoietic stem cells, reproductive organs, autografts or xenografts;
- Infections caused by other pathogens (including health care-associated infections);
- Risks of transmission of cancer; or
- Assessment or testing of solid organ donors from other States and Territories.

2 ASSESSMENT OF POTENTIAL DONORS FOR BLOOD BORNE VIRUS

All donor notifications should be made to Donation Specialist Nurses through their paging service (Telephone 9963 2801).

The Donation Specialist Nurse must review all potential donors’ available medical records to identify evidence of an infectious disease or documentation of established risk behaviours associated with BBV. This includes a standard questionnaire relating to risk of BBV completed with a next of kin and/or other person who has an established relationship with the donor (e.g. the donor’s general practitioner). This must be in accordance with the Australian Transplant Coordinator Association (ATCA) and Transplantation Society of Australia and New Zealand (TSANZ) Confidential Organ Donation Referral Form. http://www.tsanz.com.au/downloads/Protocols_Appendix1.pdf
The Donation Specialist Nurse is responsible for communicating all relevant information that has been collected in the donor assessment and testing process to the medical consultant of the NSW Organ and Tissue Donation Service (OTDS).

See Attachment 1 Blood Borne Virus testing – summary flowchart page.

2.1 Testing

In NSW HIV infection is currently an *absolute contraindication* for organ donation. Testing for HBV and/or HCV co-infection is therefore not warranted where the donor is known to be HIV positive either on serology or NAT assay.

As pathology testing (especially nucleic acid testing - NAT) can be a rate-limiting step in the assessment of a donor’s suitability, appropriate specimens should be sent to the laboratory at the earliest opportunity. Where appropriate, this includes sending specimens for testing before organ retrieval has been confirmed.

All potential organ donors must have serology testing for BBV as follows:

- Antibody to Human Immunodeficiency Virus, Type 1 (anti-HIV-1 Ab);
- Antibody to Human Immunodeficiency Virus, Type 2 (anti-HIV-2 Ab);
- Antigen testing for Human Immunodeficiency Virus, usually as part of the combined
- Hepatitis B surface antigen (HBsAg);
- Hepatitis B core antibody (anti-HbcAb);
- Hepatitis B surface antibody (HBsAb);
- Antibody to Hepatitis C (anti-HCV Ab); and
- Human T-cell Lymphotropic Virus I/II (at the clinician’s discretion)

Other diagnostic tests, for example Cytomegalovirus IgG antibody, Epstein-Barr Virus IgG antibody, and syphilis antibody (TPHA) may also be indicated.

**Nucleic Acid Testing (NAT) for BBV**

NAT allows detection of HBV, HCV or HIV, whereas routine serology detects antibody response, which may persist for life after infection. NAT assays are especially useful in recent infection where serology may be negative (in the serological window period), in the presence of high amounts of virus. NAT also assists with assessment of discordant serological assays.

For deceased organ donors at increased risk of having BBV (Increased risk donors), urgent (often after hours) testing may be performed with the aim of providing a NAT result before organ retrieval.

A blood sample for NAT is routinely taken on all donors in NSW, however when this is performed during normal working hours the result is usually not known until after transplantation.

A negative NAT assay does not completely eliminate the possibility of recent infection. NAT assays also have periods when they are negative following acute infection (i.e. NAT “window” periods). In practice, the risk of infection from screened donors has been extremely low in this
NAT window period. The current NAT window periods for inability to detect virus are approximately as follows:

- HBV: 21 days
- HIV: 9 days
- HCV: 7 days

For deceased donors assessed to be at increased risk of BBV, testing must be performed prospectively so that the NAT result is available at the time of organ allocation. In all other cases, the test is performed after organ transplantation, if the timing of the request does not align with the laboratory schedule for running NAT. Every effort should be made to transport specimens to the laboratory by the recommended time, in order to facilitate timely availability of results. Communication with the laboratory during this time is essential in optimizing outcomes for the organ transplant process.

Further information about NAT for HIV, HBV and HCV is available via the Australian Society for HIV Medicine web site [http://testingportal.ashm.org.au](http://testingportal.ashm.org.au)

**Specimen sampling (serology and NAT)**

- For donors declared dead by brain death criteria, all blood samples should only be drawn after brain death has been confirmed.
- For potential donation after cardiac death (DCD) donors, it is acceptable to test blood that is drawn in the pre-mortem period.
- Where the donor is a neonate (less than 28 days of age), testing should also be performed on a maternal blood specimen.
- Where the specimen may have unusual characteristics, including donors who have had massive blood and/or blood product transfusion, it is essential to indicate the underlying condition on any request form accompanying the specimens.
- If the donor has received greater than 50% of blood volume in blood product transfusion the sample is unsuitable for serology and NAT testing. A pre-transfusion sample should be provided to the laboratory.
- The Donation Specialist Nurse should liaise with the hospital staff as to proper sampling, labeling and transport.
- The Donation Specialist Nurse should liaise with the laboratory regarding the increased risk donor clinical condition, and to determine when NAT result is expected. This information should be communicated to the medical consultant of the OTDS and relevant transplant units as required.

**3 DECIDING TO PROCEED WITH ORGAN DONATION**

The on-call medical consultant of the OTDS is responsible for the decision as to the medical suitability of the potential donor and proceeding with organ retrieval. This will be in consultation with the transplant team, and where appropriate with the on-call OTDS laboratory consultant.

Where there are risk factors or any positive diagnostic serology or NAT assays, the on-call medical consultant for the donor agency or the transplant clinician should consult with the on-call infectious disease consultant of the SEALS donor testing laboratory and/or Chair of the NSW Health Blood Borne Virus Panel, or delegate.
Organs from donors who are likely to be infectious, or for whom infectious status cannot be reliably determined may be allocated according to current allocation protocols of The Transplantation Society of Australia and New Zealand.


The Transplant Unit retains the discretion to accept, or decline the offer of an organ from an infected or potentially infected donor. It is important the retrieval team is aware of the infectious status of the donor.

3.1 Donors who are regarded as non-infectious for donation purposes

These include individuals for whom:

- No risk behavior or risk factors have been identified and serology is negative; OR
- Risk behavior occurred (reliably reported) more than six months ago and serology is negative; OR
- Risk behaviour occurred (reliably reported) between two and six months ago and both serology and NAT are negative; AND
- There is no clinical evidence of active infection.

In these cases, organ procurement can proceed and organs can be allocated according to usual protocols if all other donor criteria are satisfied. The caveat still applies that false negative ("window period") serology and NAT assays can occur in these circumstances. However, the above donors represent as practically as possible, donors who are not infected with HIV, HBV and HCV.

3.2 Donors with identified BBV risk factors (increased risk donors)

- Decisions about the suitability of organ retrieval from these donors may require both serology and NAT.
- Newly-acquired infections may not be detected by NAT if the acute infection occurred within the NAT assay window periods (see above).
- Depending on laboratory timetables for NAT, it may be necessary for the NSW OTDS to request urgent out-of-hours testing of specimens from potential organ donors. Urgent testing produces a result within 8 hours of specimen receipt.

These donors may proceed to organ procurement if there are recipients for whom risk of infection is substantially outweighed by the urgency for transplantation, in accordance with current TSANZ allocation protocol available at


3.3 Donors who are known to be infectious

- For a donor already known to be infected with HBV and/or HCV, the donor agency should be notified and the specimen should be sent directly for NAT assay for HIV, HCV and HBV to confirm the known infection/s, and to test for the other BBVs. It will be possible in future to genotype the HCV infection, to allow directed donation to recipients with appropriate genotypes.
- The Hepatitis C Register should be consulted for potential consenting recipients for a Hepatitis C positive organ.

Potential organ donors who have positive serology, NAT or clinical evidence of active HBV or HCV infection may proceed to organ donation if there are recipients for whom risk of infection is substantially outweighed by the urgency for transplantation or where recipients have pre-existing infection and have expressly consented to receiving such an organ.


If a deceased donor is diagnosed with HIV the State Medical Director of the NSW OTDS should refer the case to the sexual health service in the local health district where the donor resided for contact tracing. Contact tracing is undertaken in accordance with Policy Directive PD2005_184 Contact Tracing Guidelines for the Sexually Transmissible Diseases and Blood Borne Viruses_ http://www0.health.nsw.gov.au/policies/PD/2005/PD2005_184.html

If a deceased donor is diagnosed with hepatitis B or hepatitis C the State Medical Director of the NSW OTDS should notify the case to the public health unit in the local health district where the donor resided. Public health unit contact details are on the NSW Health website at: http://www.health.nsw.gov.au/Infectious/Pages/phus.aspx

4 ASSESSMENT OF POTENTIAL RECIPIENTS ON THE TRANSPLANT WAITING LIST

The HIV, HCV and HBV status of potential recipients placed on a transplantation waiting list must be determined as this affects decisions about organ allocation of both infected and uninfected organs. All recipients on the waiting list should be offered immunisation according to national recommendations for solid organ transplant recipients (see the current edition of the Australian Immunisation Handbook available at www.immunise.health.gov.au)

It may be necessary to periodically retest negative potential recipients to ascertain their current infection status depending on the length of time on the waiting list and any ongoing risk behaviour.

Immediately prior to transplantation, a sample of serum should be collected from the recipient and stored according to National Pathology Accreditation Advisory Council guidelines Requirements for the Retention of Laboratory Records and Diagnostic Material (Fifth Edition 2009).
5 RECIPIENT CONSENT

There is a legal requirement for the transplant unit to inform a potential recipient of the risks and consequences of accepting versus not accepting an organ. In order for consent to be valid there should be disclosure to the recipient of all material risks to which the patient may attach significance that may be associated with accepting a particular organ. See PD2005_406 Consent to Medical Treatment – Patient Information http://www0.health.nsw.gov.au/policies/PD/2005/PD2005_406.html

In many circumstances, decisions about transplantation are made quickly and this may make it difficult for a potential recipient to carefully evaluate the risks and benefits. To provide potential recipients with reasonable time to consider these matters, the possibility of accepting a potentially infectious organ should be discussed with the recipient at entry onto the waiting list for transplantation and periodically thereafter.

Regardless of the results of the donor screening and testing process, the transplant team should ensure that the potential transplant recipient understands that:

- No pathology test that is performed on a donor is entirely capable of reducing risk of transmission to nil, although all efforts are taken to reduce risk of BBV transmission, effectively resulting in extremely low risk,
- There is a small chance that screening of the donor has not identified a serious infectious disease;
- Tests are not performed for all known infectious diseases; and
- There are rare instances where transplantation results in the transmission of infections that have not been described before.

At the time of transplantation where transmission of an infectious disease from a donor is thought to be possible, the transplant team should discuss the risks and benefits with the potential recipient presenting case-specific information. Information should include:

- That the infection that may be transmitted and the likely risk of transmission;
- The potential severity of infection;
- The ease of treating the infection should it occur;
- Whether all testing of the donor has been completed;
- The risk of significant morbidity or mortality without transplantation at this time; and
- The benefit of accepting this organ at this time.

The consent form completed at the time of transplant must expressly include recipient’s acceptance of a potentially infectious organ.

6 SURVEILLANCE OF BBV INFECTION IN TRANSPLANT RECIPIENTS

The transplant unit should determine whether transmission of blood borne viruses may have occurred by performing serological testing of the recipient, as clinically indicated. All transplant–associated infections including evidence that transmission of infection from donor to recipient may have occurred must be reported by the transplant unit to:
7 DOCUMENTATION

Documentation related to donor assessment (e.g. ATCA Confidential Donor Referral Form), recipient consent, and offer and allocation processes should address risk of transmission of Blood Borne Virus.

Investigations that have been performed but for which no report has been issued should be noted.

Organs for transplantation should be accompanied by a de-identified summary of the donor’s relevant medical records that documents risk factors or clinical evidence of infection.

8 LIST OF ATTACHMENTS

1. Blood Borne Virus testing – summary flowchart
2. Implementation Checklist
Attachment 1: Blood Borne Virus testing – summary flowchart

Risk assessment using ATCA/TSANZ Referral Form

No risk factors

Most recent exposure more than 6 months ago

Risk factors

Most recent exposure less than 2 months ago

Most recent exposure between 2 and 6 months ago

Serology.

Negative serology and negative NAT (if result known)

Donor unlikely to be infectious

Proceed with organ retrieval

Positive serology*

Hep B surface antibody detection with negative hep B core antibody and no hep B surface or e-antigen indicates prior vaccination and is not considered positive serology

Donor Rejected

Urgent NAT and serology

Positive serology and/or positive NAT

Infectious donor

HBV or HCV infection

Proceded with organ retrieval according to current TSANZ guidelines for organ allocation in HBV/HCV donors

May still consider organ retrieval but requires further discussion between relevant consultants

NAT "Windows"
- HBV: 21 days
- HIV: 9 days
- HCV: 7 days

Positive serology and negative NAT

Serology and NAT unable to definitively exclude infections

HIV infection

Donor Rejected

Issue date: September-2013
## Attachment 2: Implementation checklist

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### IMPLEMENTATION REQUIREMENTS

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