Changes in this version

Addition of need to further assess potential Tissue Donors who have received Human Derived Products. Reference to Kidney asymmetry. Reference to SOP4746 – DCD Heart donation. Amendment to lung age criteria. Amendment to Pancreas Criteria.

Policy

To maximise the potential for organ donation from deceased donors, every eligible organ donor should become an actual donor where appropriate. However, to prevent families being approached needlessly when organ donation would never occur, it is important to define those characteristics of potential deceased donors that preclude donation in any circumstance. These guidelines are therefore intended primarily for the Specialist Nurses in Organ Donation.

It should be recognised that some diseases in the donor, notably cancers and infections (whether present at the time of donation or in the history) may be transmitted by organ donation. In this context, a significant infection is one that may result in significant morbidity or death of the recipient despite appropriate treatment. The decision to use organs from such donors must be made following an assessment of the risks and benefits of using such organs. SaBTO has published guidance to help the surgeon make an informed risk assessment. Organs from such donors may be offered but the SNOD should ensure the past medical history is made available to the recipient team.

Because NHSBT will not hold all the relevant information about the potential recipient to make a balanced risk assessment to decide whether to use an organ from a higher risk donor, NHSBT will continue to offer those organs so that the surgeon can, after consultation and seeking expert advice, make a balanced risk assessment whether to accept the offered organs.

Where there is a suspicion but unconfirmed diagnosis of a cancer or of a significant infection, this concern must be passed on to the recipient team.

It should be recognised that it is the responsibility of the recipient surgeon to decide whether to accept an organ and this decision will depend on both donor and recipient factors. Organs from any donor will carry some degree of risk and the risks associated with transplantation must be balanced against the benefits of transplantation and the risks of remaining on the waiting list pending a further organ offer.

The criteria listed below were drawn up by a group of transplant surgeons, physicians, intensive care clinicians and specialist nurses in organ donation and are based on national guidelines, past experience and published data.

As with all guidelines, these should be combined with clinical judgement and, if a clinician feels that a person excluded by this list should be offered the opportunity to donate, then the family should be approached for consent/ authorisation.

Advice on donation from those deceased donors with cancer or a history of cancer is given by the recent SaBTO Guidance (2020) which advises that organs from donors with primary CNS tumours may be used unless the tumour is a lymphoma (even if the lymphoma is considered a primary intra-cerebral lymphoma). The presence of a CSF shunt does increase the risk of transmission, but this additional risk is estimated to be less than 1%. The recent SaBTO guidance categorises the risk of CNS cancer transmission into Intermediate or Low Risk depending on grade (SaBTO 2020).

SaBTO (2020) guidance can be found using the link below:

https://assets.publishing.service.gov.uk/media/5fe49ac68fa8f56af97b1e6d/transplantation_of_organs_from_deceased_donors_with_cancer_or_a_history_of_cancer-revised_FINAL44266_JNcw_cw.pdf

Where absolute or organ specific contraindications apply, those organs are also not suitable for offering to other European countries.

Absolute Contraindications to consideration of deceased donation

- Age ≥85 years (on or after their 85th birthday)
- Primary cerebral lymphoma
- All secondary intracranial tumours
- Any active cancer with evidence of spread outside affected organ within 3 years of donation *
- Malignant Melanoma - please refer to section below on when donors with malignant melanoma may be considered **
- Active (not in remission) haematological malignancy (myeloma, lymphoma, leukaemia)
- Definite, probable or possible case of human transmissible spongiform encephalopathy (TSE including CJD and vCJD, individuals whose blood relatives have had familial CJD, other neurodegenerative diseases associated with infectious agents.
- Tuberculosis: active and untreated or during first 6 months of treatment. (Organs can be considered for transplant if the donor has received a minimum of 6 months of appropriate anti-tuberculous treatment, unless the isolate is found to be drug-resistant).
- West Nile Virus (WNV) infection
- HIV disease (not HIV infection only***)
- A history of infection with Ebola virus
- Bacillus anthracis (Anthrax)
- Dengue Virus
- Proven Corona Virus without recovery (Corona Virus infection includes Covid 19, SARS and MERS)****
- Rabies
- Yellow fever
- Viral haemorrhagic fevers - including Lassa, Ebola, Marburg and CCHF viruses.
- Chikungunya virus (*Donation can be considered 6 months post recovery)*
- Progressive Multifocal Leukoencephalopathy (PML)
- Zika virus (Donation may be considered 6 months after recovery)
- Systemic infection with candida/aspergillus/other fungi/endemic mycoses

* active means not in remission; spread outside affected organ includes spread to lymph nodes. Localised prostate, thyroid, in situ cervical cancer and non-melanotic skin cancers are acceptable as possible organ donors. It is appreciated that the term ‘active cancer’ is imprecise; the term has been agreed to identify those cancers where there is a probability that cancer will be transmitted to the recipient.

** Malignant Melanoma without spread is considered high risk in terms of cancer transmission. Donors with a history of malignant melanoma diagnosed during donor characterisation should not be used. Organs from donors with melanoma diagnosed over 5 years previously, with no nodal spread and Breslow depth less than 0.8mm may be usable only if precise information on staging, therapy, follow-up and recurrence- free survival are available, and evaluation by the dermato-oncologist concludes there is a low probability of recurrence and metastasis.

*** HIV infection refers to people who have infection with HIV but none of the associated complications, i.e. AIDS. Organs from donors with HIV are highly likely to transmit the infection to the recipient and so are used only for those recipients who are already infected. Such recipients must be informed and consented about the risks of possible super-infection and transmission of

other infectious agents that may be present in HIV infected patients and whose effects may be exacerbated by immunosuppression

**** Refer to **POL304** for latest policy guidance.

Advice on use on higher risk donors: There is clear guidance on the use of such organs from SaBTO and other bodies, and clinicians are reminded that, in these situations, a risk assessment must be made and the surgeon is strongly advised to seek advice from colleagues (surgeons, physicians, microbiologists and others as appropriate) and document the outcome of discussions in the records. The potential recipient must also be appropriately counselled and this too documented.

Extract from SaBTO Guidance concerning derogation of exclusion criteria:

15 Exceptional use of organs and tissues from donors potentially or known to be infected Derogation of exclusion criteria for donors who carry an infection risk

15.1 We acknowledge the overwhelming clinical need for, and shortage of, organs suitable for transplantation in the UK. The unnecessary loss of potential organs needs to be avoided at all times and has been addressed in part by the guidelines for testing described above.

15.2 We accept that there may be clinical need for transplantation of such urgency that it may be appropriate to consider the use of organs and tissues for life-preserving purposes from donors who would not otherwise be considered eligible to donate, due to a known or perceived infection risk. Potential organs from such donors should be offered to the transplant community. Fully informed consent to such a procedure is required from the recipient of such transplantation and all measures for risk reduction, including onward transmission, must be taken. Transplants of this nature are likely to be infrequent. Intensive immediate post-transplant monitoring and long-term follow-up of the infection status of recipients should be set in place and the long-term outcome of the recipient recorded centrally by the transplant community.

Organ specific contraindications

In addition to the absolute contraindications a number of organ specific contraindications have been identified by each NHSBT Solid Organ Advisory Group to assist in the assessment of a potential organ donor, these are listed below. Each contraindication for organs from deceased donors is specific to the organ listed and does not preclude the donation of any other organ. In some cases, individual transplant units have developed further contraindications.

Liver

- Acute hepatitis of viral, drug or other known aetiology
- Serum AST or ALT>10000 IU/L (if of liver origin)
- Cirrhosis
- Portal vein thrombosis
- Metabolic diseases that would be of harm to the recipient and not treatable (such as haemophilia A and B, inborn errors of metabolism such as oxaluria, tyrosinaemia)
- Anti-phospholipid Syndrome
- Idiopathic Thrombocytopenia (ITP) (relative contraindication)

Bowel

- DCD donors
- DBD donor age ≥60 years (on or after their 60th birthday) **or** weight of 90kg or more
- Underlying chronic intestinal disease
- Intra-abdominal sepsis
- For abdominal wall/fascia donation: Extensive surgical scars/damage to the abdominal wall/fascia
- Anti-phospholipid Syndrome

Kidney

- Chronic kidney disease (CKD stage 3B or worse, eGFR<45)
- Long term dialysis (that is, not acute relating to acute illness)
- Renal malignancy: Prior kidney tumours of low grade and previously excised would not necessarily exclude donation
- Previous kidney transplant (> 6 months previously)
- The inferior kidney where there is significant asymmetry in function

Pancreas

- Insulin dependent diabetes (excluding ICU associated insulin requirement)
- Non-insulin dependent diabetes (Type 2)
- Necrotising Pancreatitis
- Portal Vein Thrombosis
- Any history of pancreatic malignancy
- Donor BMI >40kg/m^2
- Donors <15kg (except where there is a small paediatric IFALD patient who requires donation of a pancreas with other abdominal organs)
- DBD donors ≥ 61 years (on or after their 61st birthday)
- DCD donors aged ≥56 years (on or after their 56th birthday)

Heart

- Age of 65 or more (on or after their 65th birthday)
- Coronary artery disease: history of chronic stable angina, myocardial infarction, CABG or percutaneous coronary intervention (PCI)
- Median sternotomy for cardiac surgery
- LVEF≤30%
- Myocarditis
- Lyme disease
- For DCD Hearts see **SOP4746** – DCD Heart Donation Process

Lungs

- DCD donor age ≥65 years (on or after their 65th birthday)
- DBD donor age ≥70 years (on or after their 70th birthday)
- Previous intra-thoracic malignancy
- Significant, chronic destructive or suppurative lung disease (those with controlled asthma are suitable donors)
- Chest X-ray evidence of major pulmonary consolidation
- Influenza with demonstrable lower respiratory tract infection
- Anti-phospholipid Syndrome

DCD Exclusion Criteria

The following criteria should be applied when considering the suitability of patients who have been referred as potential DCD organ donors. Patients who meet any of the criteria below are regarded as unsuitable for DCD donation at present. These criteria may be over-ruled, and organs offered for transplant should there be good reason to believe that transplantation of an organ may proceed.

- Patients aged >75 unless they are dying of a neurological condition
- Patients aged 70 - 75 unless they are dying of either a neurological condition or respiratory disease
- Patients aged >70 dependent on RRT
- Patients aged >70 with CKD 3b or greater
- Patients aged >40 with a current clinical diagnosis of multi organ failure ***
- Patients with a current clinical diagnosis of ischaemic bowel or faecal peritonitis
- Patients with a current clinical diagnosis of Septicaemia or Sepsis with severe multi organ dysfunction ***
- Patients with previous cancer in the last 5 years (except Primary CNS cancer, localised prostate, thyroid, in-situ cervical cancer and non-melanotic skin cancers)

***If a potentially transplantable organ is unaffected by MOF or Sepsis the patient should not be excluded and organ offering should be undertaken as per age related offering guidance

As previously stated, these guidelines are to support the assessment of a potential organ donor when considering DBD or DCD donation and should be applied with clinical judgement and in conjunction with the documents below. Quick access to guidance is also available on the ODT website (https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/)

NHSBT/BTS Guidelines for Consent for Solid Organ Transplantation in Adults (2013)
https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

SaBTO microbiological safety guidelines 2020; Guidance on the microbiological safety of human organs, tissues and cells used in transplantation.
https://www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation

SaBTO Position statement on West Nile Virus
https://www.gov.uk/government/publications/west-nile-virus-and-solid-organ-transplantation-sabto-statement

SaBTO Guidance on the Transplantation of Organs from Deceased Donors with cancer or a history of cancer 2020
https://www.gov.uk/government/publications/transplantation-of-organs-from-donors-with-a-history-of-cancer

Aide memoire

The Aide memoire is now available at the link below. This quick reference guide is designed for transplant clinicians to help decision-making when considering the use of organs for transplantation from donors with infection, malignancy and other potentially transmissible diseases.

This list is not exhaustive and the presence or absence of a disease in this document does not imply the appropriateness or otherwise of using organs from such a donor.

The ultimate decision to use any organ for transplantation rests solely with the transplant clinician in consultation with and with the consent of the patient.

However, we strongly recommend that, where there is any uncertainty, the transplant team seek advice from a clinician with relevant expertise (e.g. microbiologist or infection specialist experienced in transplantation; oncologist or oncological surgeon) regarding the possible risks and consequences of donor transmitted disease.

https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/sabto-aide-memoire/

TISSUE DONATION ASSESSMENT PRIOR TO REFERRAL TO NATIONAL REFERRAL CENTRE (NRC)

The criteria below are to help staff carry out an initial assessment of the deceased to see if they might be a suitable donor. If you require any further assistance, please visit: http://www.transfusionguidelines.org.uk/dsg

1. MAIN MEDICAL CONTRAINDICATIONS TO ALL TISSUE DONATION:

- History of Haematological malignancy
- History of metastatic malignant melanoma
- History of chronic viral hepatitis or HIV infection
- Diseases of unknown aetiology if cause unclear e.g. Multiple Sclerosis (not to be confused with Auto-Immune Disease)
- Risk factors for Creutzfeldt-Jacob's disease or its variant (for example dementia / progressive memory loss of unknown origin)
- Previous Ocular Tissue Transplant
- Neurodegenerative disease of unknown aetiology (Dementia, Alzheimer's, Parkinson's.)
- Some Behavioural/Lifestyle risks

2. SPECIFIC CONTRAINDICATIONS TO CORNEAL DONATION:

- Primary (e.g. Retinoblastoma) and metastatic ocular malignancies
- Intrinsic Eye disease: Active ocular inflammation or infection and any congenital or acquired disorders of the eye, or ocular surgery or trauma, that would preclude successful graft outcome
- Ocular Herpes
- Systemic viral and fungal infections

3. SPECIFIC CONTRAINDICATIONS TO MULTI TISSUE DONATION WITHOUT OCULAR DONATION

- Systemic infection
- Malignancy – exceptions are: Basal Cell Carcinoma, Non-haematological premalignant disease such as Barratts Oesophagus and Carcinoma insitu – eg: Ductal CIS of breast

FOR INFORMATION – CONSIDERATIONS FOR TISSUE DONORS:

- For heart tissue - call the NRC for paediatric donors prior to consent to ascertain demand for smaller valves
- For corneas it will depend on age and eye conditions
- For skin donation - consider site of tattoos and condition of the skin. The Donor **MUST** weigh over 9 stone / 57 Kg
- The considerations for Bone, Tendons, Arteries and Meniscus can vary depending on the age of the donor, previous surgery, medical history, and current Tissue Banking requirements.
- Where the donor has received any human derived products such as beriplex please seek clinical advice from NRC.

For Specialist Nurses in Organ donation please refer to SOP5981 for specific requirements

If in doubt regarding whether you should offer Donation please don't hesitate to contact the **National Referral Centre (NRC) on 0800 432 0559 (opening times 08.00 – 20.00). If out of normal working hours leave a message and someone will call you back.**