

## **Changes in this version**

Amendment to age and weight contraindication for Bowel Donation

### **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 not 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, notably cancers and infections, in the donor (whether present at the time of donation or in the history) are at risk of being transmitted by organ donation. In this context, a significant infection is one that will have a significant impact on the morbidity or mortality 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 all donors will carry some degree of risk and the risks associated with transplantation must be balanced against the benefits of transplantation and the risks of awaiting a further offer of a donor organ.

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 used 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 (2014) 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 intracerebral 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 cancer transmission into Minimal, Low and High Risk (SaBTO 2014).

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

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**Absolute Contraindications to consideration of deceased donation**

- Age  $\geq$ 85 years (on or after their 85<sup>th</sup> birthday)
- Primary intra-cerebral lymphoma
- All secondary intracerebral tumours
- Any active cancer with evidence of spread outside affected organ within 3 years of donation \*\*
- Malignant Melanoma
- 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 a recipient has received a 6-month course of chemotherapy, unless the isolate is found to be resistant to anti-tuberculosis drugs).
- West Nile Virus (WNV) infection#
- HIV disease (not HIV infection only\*)
- A history of infection with Ebola virus
- Bacillus anthracis (Anthrax)
- Dengue Virus
- Middle East Respiratory Syndrome
- Severe Acute Respiratory Syndrome (SARS)
- 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*)

# WNV infection is very uncommon and there have been, as yet, no known cases in the UK, but may be transmitted by organ transplantation although infection is often asymptomatic, and infection may be identified after donation has occurred. Refer to the SaBTO guidance (referenced at the end of this policy).

\* HIV infection means people who have infection with HIV but none of the associated complications. 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 carriers of the virus. Such recipients must be informed and consented about the risks of possible super-infection and transmission of other infective agents that may be present in HIV infected patients and whose effects may be exacerbated by immunosuppression.

\*\* 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.

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 should be made and the surgeon is strongly advised to seek advice from colleagues (surgeons, physicians, microbiologists and others as appropriate) with the discussions and document the outcome in the records. The potential recipient must also be appropriately counselled and this too documented.

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Extract from SaBTO Guidance concerning derogation of exclusion criteria:

10. *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*
- 10.1 *We acknowledge the overwhelming clinical need for, and shortage of, organs suitable for transplantation in the UK. The loss of potential organs needs to be avoided at all times and has been addressed in part by the guidelines for testing described above.*
- 10.2 *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*

### **Relative Contra-indications**

- Lyme disease
- Listeria
- MMR - acute
  
- **Aspergillosis** (or other systemic fungal infections are contraindications for transplantation unless a specific risk assessment is carried out and appropriate recipient antifungal prophylaxis is prescribed.). Specialist microbiological advice should be sought for an accurate risk assessment to be made.
  
- Ongoing systemic **fungaemia** (Systemic infection defined by fungaemia may be associated with mycotic aneurysm at vascular anastomoses. On-going fungaemia is an absolute contra-indication to donation of organs and tissues but specialist microbiological advice should be sought for an accurate risk assessment to be made).

### **Organ specific contraindications**

In addition to the absolute contraindications a number of organ specific contraindications have been developed by each NHSBT 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)
- Idiopathic Thrombocytopenia (ITP) (relative contraindication)

### **Bowel**

- DCD donors
- DBD donor age  $\geq 60$  years (on or after their 60<sup>th</sup> 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

### **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)

### **Pancreas**

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

### **Heart**

#### Urgent:

- Age of 65 years or more (on or after their 65<sup>th</sup> birthday)

#### Non-urgent:

- Documented coronary artery disease (e.g. confirmed history of MI, CABG or percutaneous stenting)
- Median sternotomy for cardiac surgery
- LVEF  $\leq 30\%$  on more than one occasion
- Massive inotropic or pressor support, but only if adequate circulating volume has been confirmed by monitoring
- Myocarditis
- Lyme disease

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## **Lungs**

- DCD donor age  $\geq 65$  years (on or after their 65<sup>th</sup> birthday) unless donor is a lifetime non-smoker, or has not smoked for 10 years or more, in which case donor age  $\geq 75$  years (on or after their 75<sup>th</sup> birthday)
- DBD donor age  $\geq 70$  years (on or after their 70<sup>th</sup> birthday) unless donor is a lifetime non-smoker, or has not smoked for 10 years or more, in which case donor age  $\geq 75$  years (on or after their 75<sup>th</sup> 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

## **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 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://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4378/guidelines\\_consent\\_for\\_solid\\_organ\\_transplantation\\_adults.pdf](https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4378/guidelines_consent_for_solid_organ_transplantation_adults.pdf)

SaBTO microbiological safety guidelines 2017; 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>

# POL188/14 – Clinical Contraindications to Approaching Families for Possible Organ Donation



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SaBTO Guidance on the Transplantation of Organs from Deceased Donors with cancer or a history of cancer 2014

<https://www.gov.uk/government/publications/transplantation-of-organs-from-donors-with-a-history-of-cancer>