

Clinical contraindications to approaching families for possible organ donation

<i>This Policy replaces</i> <i>POL188/5.1</i>	Copy Number
	Effective 18/12/2015
Summary of Significant Changes Additional absolute contraindication: History of infection with Ebola virus	

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 past 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. If the suspected cancer or infection is one that is listed as an absolute contra-indication for donation, then the organs from the potential donor may still be offered but the SNOD must ensure that the recipient team are made aware of the possibility of the cancer being present.

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.

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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 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 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.

Absolute Contraindications to consideration of deceased donation

- Age \geq 85 years (on or after their 85th birthday)
- Primary intra-cerebral lymphoma
- All secondary intracerebral tumours
- Any active cancer with evidence of spread outside affected organ within 3 years of donation **
- Melanoma (except completely excised Stage 1 cancers)
- 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.
- TB: active and untreated
- West Nile Virus (WNV) infection#
- HIV disease (but not HIV infection*)
- A history of infection with Ebola virus

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.

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.

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*

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- 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*

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)

Bowel

- DCD donors
- DBD donor age ≥ 56 years (on or after their 56th birthday) **or** weight of 80kg 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)

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Pancreas

- Insulin dependent diabetes (excluding ICU associated insulin requirement)
- Non-insulin dependent diabetes (Type 2)
- Any history of pancreatic malignancy
- Donor BMI >40kg/m²
- Donors <15kg (except where there is a small paediatric IFALD patient who requires donation of a pancreas with other abdominal organs)
- DBD donors ≥ 66 years (on or after their 66th birthday)
- DCD donors aged ≥56 years (on or after their 56th birthday)

Heart

Urgent:

- Age of 65 years or more (on or after their 65th birthday)

Non-urgent:

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

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

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.

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 (<http://www.odt.nhs.uk/transplantation/guidance-policies/>):

NHSBT/BTS Guidelines for Consent for Solid Organ Transplantation in Adults (2013)
http://www.odt.nhs.uk/pdf/guidelines_consent_for_solid_organ_transplantation_adults.pdf

SaBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation (2011)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121497

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

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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>

Council of Europe: Criteria for preventing the transmission of neoplastic diseases in organ donation. Council of Europe Publishing (2006)

<http://128.121.10.98/coe/pdfopener?smd=1&md=1&did=514115>

Council of Europe: Guide to the quality and safety of organs for transplantation

<https://www.edqm.eu/en/organ-tissues-cells-transplantation-guides-1607.html>