SaBTO

Advisory Committee on the Safety of Blood, Tissues and Organs

TRANSPLANTATION OF ORGANS FROM DECEASED DONORS WITH CANCER OR A HISTORY OF CANCER

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Recommendations

1. ***Organs from deceased donors with some types of cancer may safely be used for transplantation.*** On the basis of the current evidence, it is recommended that organs from deceased donors with certain current and past cancers may safely be used.

2. ***Risks of cancer transmission must be balanced against the risks of dying without transplantation.*** The risk of inadvertent cancer transmission must be balanced against the risk of a patient dying waiting for a transplant or becoming too sick for the procedure to be successful if the organs are not used. This decision must be made by the recipient surgeon having considered and discussed the risk/benefit with the patient. The surgeon may seek the advice of colleagues; there must be clear records of such discussions prior to their use.

3. ***The risk of transmission of a cancer to a recipient in the UK from a donor not previously known to have a cancer is around 0.05% (1 in 2000).*** Transmission of a previously undiagnosed cancer from a donor to a recipient does occur and potential transplant recipients must be advised that UK data (2001-2010) suggest that the risk of transmission of cancer from a donor not known to have a cancer at the time of retrieval is around 1 in every 2,000 organs transplanted [1].

4. ***Past or current donor cancers can be divided into contra-indicated, high, intermediate and low risk****.* Characteristics of these cancers are summarised in the Tables below. For many cancers there are insufficient data to estimate a risk.

5. ***Potential recipients must give informed consent.*** Surgeons must ensure that the recipient has given informed consent, which must include the understanding that transplanted organs may rarely transmit cancer and that organs from some donors with a history of current or past cancers may be used. Where potential donors have a history of cancer, the surgeon may wish to discuss use of these organs with colleagues and must seek specific consent from the intended recipient. Where mental incapacity exists (such as where the potential recipient is on a ventilator), the next of kin must be consulted. In the case of child below the age of consent the parents must be consulted. Children and young people should be involved as much as possible in decisions about their care, even when they are not able to make decisions on their own.

6. ***Recipient wishes must be respected****.* Whether or not a potential recipient is willing to accept an organ from a donor with cancer must be discussed before wait-listing rather than at the time of organ offer. The recipient must be allowed to change their mind without detriment to their care.

7. ***The organ retrieval team must make every reasonable effort to exclude previously recognised cancer or cancer spread during the retrieval process****.* The retrieval team must, wherever appropriate, undertake a full review of the clinical records and imaging reports available prior to retrieval (and, if expertise permits, the imaging itself) and must perform a full examination of the abdominal and thoracic cavities during the retrieval process.

8. ***Histological characterisation of all tumours prior to implantation is desirable*** although it is recognised that, in some cases, it may not be feasible to delay implantation until the histology reports are available. It must also be appreciated that histological assessment based on rapidly fixed specimens is less reliable than assessment after full examination following full fixation and sometimes after additional staining.
9. ***NHS Blood and Transplant (NHSBT) must maintain a register of outcomes of transplants from donors with cancer.*** The need for clinicians to identify and report when organs from donors with current or past cancers are used and for NHSBT to maintain a registry and report outcomes is a legal obligation. A report on donor transmission events and their outcomes must be published regularly (e.g. five-yearly).
10. ***The risk of transmission of cancer from donors with High Grade (Grade 4) Central Nervous System (CNS) tumours to recipients is 2.2%.*** The overall risk of cancer transmission from deceased donors with high-grade tumours (grade 4, e.g. Glioblastoma) has been estimated to be around 2.2%. The presence of a cerebrospinal fluid shunt will increase the risk of extra-neural metastasis but this is estimated at less than 1%. The shunt track must be inspected carefully at the time of retrieval.
11. ***The optimal management of patients in whom a high-risk donor cancer has been identified after implantation or when there is evidence of cancer transmission is uncertain.*** The decision whether to remove the organ, modify immunosuppression and/or offer chemo- or radiotherapy will depend on the type of cancer, the organ transplanted and the interval between transplantation and recognition of the cancer, and must take into account the recipient's wishes.
12. ***Transmission events must be reported immediately upon recognition to NHSBT.*** NHSBT will inform clinical teams looking after recipients of other organs from that donor, and are responsible for reporting to the Competent Authority.

Inadvertent transmission of cancer is inherent in organ transmission and such an occurrence does not necessarily imply any error. However, all occurrences of transmission of donor cancer will be fully and promptly investigated by NHSBT and any lessons learned will be passed on to relevant parties.

Members of the working group responsible for producing and revising this document are shown in Appendix 1.

Revisions in this edition

1. Change in named brain tumours in Table 1 in light of revised WHO nomenclature.
2. Clarification of advice for prostate cancer.
3. Change in advice for renal carcinoma stage pT1b, reflecting further expert opinion and literature review.
4. Revision of advice for melanoma, to include only pT1a tumours (Breslow depth <0.8mm), reflecting further evidence.
5. Revision of advice for stage 1 breast and colon cancer to exclude cases with any nodal spread.
6. Removal of advice for ovarian cancer due to paucity of evidence.

Introduction

The number of people who would benefit from a solid organ transplant is increasing, as more people develop end-stage kidney, liver, heart, lung, pancreas or intestinal failure. Although the UK, as many other countries, has seen an increase in the number of deceased donors, the rate of increase has failed to match the increase in the need for a transplant. Furthermore, the quality of the organs retrieved is falling, as donors become higher risk because of increasing age and increasing obesity. The rate of death on, or removal from, the waiting lists (which is up to 20% for heart, lung and liver candidates) underestimates the short-fall.

Organs donated by deceased donors carry many risks and these include transmission of infection and/or cancer. Cancers in the recipients may be divided into donor-transmitted cancers and donor-derived cancers. Donor-transmitted cancers (DTC) are those cancers which are present in the donated organ and tissue at transplantation, whereas donor-derived cancers are those that are of donor origin but develop *de novo* in the graft after transplantation. Differentiation between these two cancers may be difficult and is usually dependent on the time interval between transplantation and identification of the cancer. These must be distinguished from recipient cancers which may be present before or develop after transplantation.

Donor assessment will allow some evaluation of the risks but the limitations of diagnostic imaging, especially in the clinical context of deceased donation, mean that while these risks can be minimised, they cannot be abolished. The donor assessment team has the responsibility of ensuring as full an assessment as possible is made within the constraints around the donation process, and the recipient surgeon has the responsibility of deciding whether to accept the donated organ(s) for that patient. The responsibilities of the surgeon are described in detail elsewhere [2]. It is important that the potential recipient is adequately counselled about the risks involved (as well as the benefits) and gives an informed consent.

To provide guidance to surgeons and patients, several organisations have published recommendations, using a variety of databases and different classifications (see Table 1). The Council of Europe Guidelines [3] classify some donors as having an unacceptable risk whereas the Disease Transmission Advisory Committee in the USA [4] suggested five levels of tumour transmission risk from nil to high (>10%), with a sixth category of "unknown risk". For those donors with high risk, it was recommended that use of organs from such donors must be discouraged "except in rare and extreme circumstances", and that informed consent was required.

These recommendations for patients in the UK are based on a review of the UK National Transplant Registry and a review of the literature. Nevertheless, it must also be appreciated that these recommendations are made on evidence from those donors with cancer that *have* donated and therefore there will be inherent biases which may affect the conclusions from the reviews of past activity. This may reflect the intrinsic suspicion that organs such as the liver and lung, prone to being the site of non-transplant-related blood-borne metastases in contrast to other organs such as the heart, thus have a higher threshold for acceptance.

We have classified the risk of cancer transmission into the following categories:

- Absolute contra-indication
- High risk (estimated at >10%)

- Intermediate risk (estimated at between 2% and 10%)
- Low risk (estimated at between 0.1% and 2%)
- Minimal risk (estimated at <0.1%).

It must be recognised that these categories are somewhat arbitrary and will need regular review as more evidence becomes available.

It must also be noted that there is no category of zero risk.

Children and young adult recipients

Balancing risk against benefit is particularly important in the case of children and young adults, where the risk of waiting list mortality may be less and longevity with a graft much greater. Hence consideration of minimal and selected low risk grafts only may be more appropriate, depending on clinical urgency and following discussion with the patient and/or their family, depending on age.

Recipients who developed donor-transmitted cancer

The UK experience of DTC was published in 2012 [1]. A DTC is one that was present in the donor, perhaps unknown, which spreads to the recipient using the transplanted organ as the vector. It may appear first in the donor organ, or remote from it. From 14,986 deceased donors there were 30,765 transplants between January 1st 2001 and December 31st 2010. Eighteen recipients developed cancers of donor origin; organs were from 16 donors (0.06%). Of these cancers, three were donor-derived cancers (0.01%). Fifteen were cancers that were DTC (0.05%). Of these 15 DTCs, six were renal cell cancer, five lung cancer, two lymphoma, one neuro-endocrine cancer and one colon cancer. These recipients underwent explant/excision (11), chemotherapy (four), and radiotherapy (one). Of 15 recipients, three (20%) recipients with DTC died as a direct consequence of cancer. Early diagnosis of DTC (diagnosed within six weeks of transplantation) was associated with a better outcome (no DTC-related deaths in 11 cases) compared with late recognition of DTC (DTC-related deaths in three of four cases). Five-year survival was 83% for kidney recipients with DTC compared with 93% for recipients without DTC (p=0.077). None of the donors from whom cancer was transmitted were known to have cancer at donation. The authors concluded on the basis of these data that the risk of inadvertent transmission of cancer was small and cannot be avoided.

Donors with Primary CNS tumour

Based on a UK review of 448 recipients of organs from 177 donors with primary CNS tumours without any evidence of tumour transmission [5], recommendations for the use of organs from potential donors with CNS tumours were published [6]. The data were obtained by reviewing the outcomes of 246 UK recipients of organs from donors with CNS tumours. It was concluded that use of kidneys from such donors was associated with a gain of eight life-years compared to waiting for another offer. These have been included in the overall recommendations above.

Role of neuro-radiology

Many donors with primary brain tumours have a diagnosis based on imaging characteristics alone. While in some cases it is possible to obtain a rapid histological examination of the brain immediately after retrieval, in many cases that is not possible. In such circumstances it is advisable to review the radiological images with an experienced

neuroradiologist to look for pathognomonic appearances of a primary brain tumour, remembering that half of all intracranial cancers are secondaries. The risk associated with using organs from donors with a radiological diagnosis alone must be interpreted in light of that expert neuroradiological opinion, but is likely to be higher than in cases where the diagnosis has been confirmed histologically.

Donors with non-CNS tumour

The risk of cancer transmission from those UK donors with a history of non-CNS tumours was published in 2014 [7]. Of 17,639 donors, 202 (1·15%) had a history of cancer including 61 donors with cancers classified by the Council of Europe Guidelines as contraindicated [3]. No cancer transmission was noted in 133 recipients of organs from these 61 donors. At 10 years from transplantation, the additional survival benefit gained by transplanting organs from donors that had been classified using European schemas as having unacceptable/high risk cancers was 944 life-years (95%CI 851, 1037) with an average survival of 7.1 years (95%CI 6.4, 7.8) per recipient. Thus, it seems reasonable to use organs from selected donors with these cancers, and comparable conclusions were reached by others [8].

Based on the UK experience and review of extensive registry data, we classify cancers in potential donors as absolute contraindications, or carrying a high, intermediate, low or minimal risk of transmission (Table 2).

Based on the limited data available, it is not possible to determine whether some donor organs are less likely to be associated with cancer transmission than others.

Although the presence of active haematologic malignancy is an absolute contraindication, low grade haematological malignancies may need further consideration. Included in this group are monoclonal gammopathy of uncertain significance (MGUS), polycythaemia vera (PV), essential thrombocythaemia (ET) and monoclonal B cell lymphocytosis (MBCL). Median survival with PV and ET is in the region of 20 years [9], and with MGUS [10] and MBCL [11] is in the region of 13 years. The behaviour of pre-existing MGUS in the recipient does not seem to be affected by transplantation or its associated immunosuppression [12]. These cancers which have a long median patient survival may have to be viewed in the context of patients' need for organs. Clonogenic stem cells normally reside in the bone marrow, but can circulate in blood and may accumulate in liver and spleen. There are few reports of transplantation in such cases, with both beneficial and harmful results [13, 14]. Discussion with a local expert in haematological malignancy is advised.

Donors with malignant melanoma

Donors with a malignant melanoma diagnosed during donor characterisation should not be used. Organs from donors with a history of melanoma should be considered higher risk of transmission. Organs from donors with melanoma diagnosed over 5 years previously, with no nodal spread and Breslow depth <0.8mm may be usable *only* if precise donor data about 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.

Management of the recipient after implantation of an organ from a donor where cancer transmission is possible

Recognition that a donor has a cancer may be made after implantation of an organ. We have identified situations where recognition of such an event has occurred when the donor has a full autopsy, when there has been a further review of the histology of a suspected lesion, when an organ has been biopsied for other reasons (such as determination of rejection) or when a tumour has developed in one recipient and histological and other information has shown this to be of donor origin.

Recommended actions to be taken when a cancer is identified in the donor after donation or when an instance of donor-transmitted cancer is confirmed or suspected

- The clinicians must immediately inform NHSBT so that clinicians looking after other recipients can be informed and management modified as appropriate.
- All recipients of organs from that donor must normally be informed.
- Under the Quality and Safety of Organs Intended for Transplantation Regulations (2012) and its amendment (2014), inadvertent transmission of donor cancer is classed as a Serious Adverse Event or Reaction and must be formally reported to NHSBT.
- There must be a formal review to determine whether the transmission could have been prevented and to ensure any lessons learned are shared.
- We recommend that NHSBT must maintain a registry so that all donors with cancer can be identified; and that the outcomes of transplants from such donors must be published at regular intervals (such as five-yearly) so guidelines can be refined. Such a registry must also include details of how the recipient was managed and the recipient outcome.

Recipient management following cancer transmission

While there are several case reports in the literature, there are few large series on which to base any recommendations about management, and many factors will determine the optimal management for an individual case:

- *Type of tumour*: the natural history of the cancer (such as whether it is likely to metastasise early) and whether it is responsive to treatment (with chemo- or radio-therapy)
- *Organ transplanted*: for example, a kidney can be removed, immunosuppression stopped, and the patient supported with dialysis whereas a heart recipient would need to wait for another suitable donor.
- *Time after transplant*: anecdotal evidence, where the organ has been removed after only a few hours, suggests that cancer transmission and metastasis can occur within hours of implantation.
- *Immunosuppression regimen*: most immunosuppressive agents will enhance the growth of cancers; however, the mTOR inhibitors (e.g. sirolimus and everolimus) have anti-neoplastic properties and are effective in the treatment of some cancers (e.g. renal cell carcinoma). It seems sensible to recommend minimising immunosuppression and/or considering the benefits of switching to an mTOR inhibitor-based regimen. Alternatively, in kidney transplantation cessation of all immunosuppression has been reported to result in the immune- mediated destruction of some tumours.

Minimisation of the risk of transmission

While it is accepted as inevitable that some cancers will be inadvertently transmitted because of the nature of the donation process, steps to minimise the likelihood must include:

- A full review of all information available at the time of donation;
- A full exploration of the thoracic and abdominal cavities during or at the end of the retrieval process;
- Histological examination of unexplained lesions prior to implantation. It must be recognised that it is not always possible to provide a full 24/7 expert histological assessment of material in a timely fashion and that conclusions from rapidly fixed specimens and without the benefit of special stains may, even in expert hands, lead to erroneous conclusions.

Screening recipients of organs from donors with cancer

It is not known whether or not it is beneficial to routinely use imaging modalities or tumour markers to screen recipients of organs from donors with a known history of cancer, or recipients of organs from donors who are found to have donated organs causing donor-transmitted cancers in other recipients. Discussion with local experts is recommended.

Further recommendations

- NHSBT must maintain a register of donors with a past or current history of cancer, and all actual and possible cases of donor-transmitted cancers, and publish outcomes on a regular basis.
- All health care professionals must be reminded of their obligations to report to NHSBT any case of possible or actual donor-transmitted cancer as soon as such a cancer is recognised.

Further reading

The Council of Europe Guide To The Quality And Safety Of Organs For Transplantation [3] summarises most of the literature on donor cancers and their transmission.

Table 1. Recommendations on the use of organs from donors with CNS tumours (2016 WHO classification)

Absolute contra-indications

- Primary cerebral lymphoma
- All secondary intracranial tumours.
- Any cancer with metastatic spread

Intracranial tumours with an intermediate risk of cancer transmission

(2.2% with an upper 95% CI of 6.4%) include WHO grade 4 tumours and equivalents:

- Atypical teratoid/rhabdoid tumour
- Choriocarcinoma.
- Diffuse midline glioma, H3K27 M-mutant
- Embryonal tumour (all subtypes)
- Giant cell glioblastoma (old classification)
- Glioblastoma (IDH wild type and IDH mutant)
- Gliosarcoma (old classification)
- Malignant peripheral nerve sheath tumour (MPNST) – grade 4
- Medulloblastoma (all subtypes)
- Medulloepithelioma
- Pineoblastoma

Intracranial tumours with a lower risk of transmission (<2%) include WHO grade 3 and equivalents:

- Anaplastic astrocytoma, IDH mutant
- Anaplastic ependymoma
- Anaplastic ganglioglioma
- Anaplastic (malignant) meningioma
- Anaplastic oligodendroglioma, IDH mutant and 1p/19q deleted
- Anaplastic pleomorphic xanthoastrocytoma
- Choroid plexus carcinoma
- Ependymoma: RELA fusion positive
- Haemangiopericytoma / solitary fibrous tumour.
- Papillary tumour of the pineal region
- Pineal parenchymal tumour of intermediate differentiation
- Malignant peripheral sheath tumour grade 3

Note: Where the diagnosis of a primary brain tumour has been made on radiological grounds alone an effort to obtain an immediate post-retrieval brain examination must be made. If histopathological examination is not possible the imaging studies must be reviewed by an experienced neuroradiologist.

Table 2. Recommendations on the use of organs from donors with non-CNS cancers

Absolute contra-indications

- Active cancer with spread outside the organ
- Active haematological malignancy

High risk (>10% risk of transmission)

- Melanoma: without spread (except as below)
- Breast: cancer other than those identified below
- Colon: cancer other than those identified below
- Kidney: renal cell cancer >7cm or stages 2-4
- Sarcoma: >5 years previously and resected
- Small cell cancer: lung/neuroendocrine
- Lung cancer: stage 1

Intermediate risk (2-10% risk of transmission)

- Kidney: Renal cell carcinoma stage 1b (pT1b) (4-7cm, Fuhrman/nucleolar grade 1 or 2) with curative surgery and cancer-free period of >5 years
- Breast: stage 1A, (pT1, N0; <20mm tumour size) with curative surgery and cancer-free period of between 5 and 10 years

Low risk (0.1-2% risk of transmission)

- Breast: stage 1A, (pT1, N0; <20mm tumour size) with curative surgery and cancer-free period of >10 years
- Colon: Stage 1A (pT1 or pT2, N0) adenocarcinoma with curative surgery and cancer-free period of >5 years
- Kidney: resected solitary renal cell carcinoma >1.0cm and <4.0 cm and Fuhrman (nucleolar) grade 1 or 2 with curative treatment and cancer free >3 years
- Melanoma: superficial spreading type, non-ulcerated, tumour thickness <0.8mm (pT1a), with curative surgery and cancer-free period of >5 years – *see text above*
- Prostate: Gleason=7, with curative treatment and cancer free >5 years
- Thyroid: solitary papillary carcinoma 0.5-2.0cm
- Thyroid: minimally invasive follicular carcinoma 1.0-2.0 cm
- Gastrointestinal stromal cancers: <2cm, <5% mitotic count, in stomach or duodenum.

Minimal Risk (<0.1% risk of transmission)

- Bladder: superficial non-invasive papillary carcinoma (pTa, G1/G2)
- Kidney: Resected solitary renal cell carcinoma <1.0cm and Fuhrman (nucleolar) grade 1 or 2
- Prostate: Gleason <6, or <7 with curative treatment and cancer free >5 years
- Skin: basal cell carcinoma
- Skin: squamous cell carcinoma with no metastases
- Skin: non-melanoma skin cancer in situ
- Thyroid: solitary papillary carcinoma (<0.5cm)
- Thyroid: minimally invasive follicular carcinoma (<1.0cm)
- Uterine Cervix: in situ cancer

Note. Only those cancers where evidence is available for analysis have been classified. Cancers not included in this guidance must be considered on a case by case basis following appropriate professional consultation.

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Appendix 1. Membership of the SaBTO Donor Organ Risk Assessment Working Group responsible for this revision

Name	Position	Role on DORA Working Group
Dr Rachel Hilton	Nephrologist	Co-Chair on behalf of SaBTO
Professor Chris Watson	Transplant Surgeon	Co-Chair on behalf of SaBTO
Professor John Forsythe	NHSBT OTDT Medical Director	Transplantation expert
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Mr Chris Callaghan	SaBTO member	Transplantation expert
Dr Gary Mallinson	SaBTO Secretariat	Secretariat support
Professor John Dark	DORA member, former SaBTO member	Transplantation expert
Katy Davison	SaBTO member	Epidemiologist
Dr Jan Dudley	DORA member	Transplantation expert
Roger Graham	SaBTO member	Lay member
Dr Gill Hardman	DORA observer	Research fellow
Dr Jayan Parameshwar	DORA member	Transplantation expert
Dr Ines Ushiro-Lumb	SaBTO member	Infectious disease expert

Appendix 2: Accountability and Governance

The SaBTO Donor Organ Risk Assessment group (DORA) will review these guidelines every 3 years, or more frequently if indicated, to ensure the information and guidance remains in line with best clinical practice.

The NHSBT DORA co-chair or nominated SaBTO member will take document revisions to the SaBTO committee for final approval.

SaBTO is responsible for the document which will be hosted on the SaBTO website. The SaBTO secretariat will ensure version control of the document and the maintenance of the SaBTO website.