

## **Changes in this version**

Clarity of role of OAS.

## **Policy**

### **NHS BLOOD AND TRANSPLANT & BRITISH TRANSPLANTATION SOCIETY**

## **Executive Summary**

1. Solid organ transplantation is associated with risk and this includes the risk of transmitted disease from the donor (infection, malignancy, immune and metabolic disease) and the risk of poor or non-function of the donor organ. The risks of transplantation with a higher risk organ must be balanced against the consequences of non-use and remaining on the waiting list without a transplant.
2. In compliance with the Quality and Safety of Organs Intended for Transplantation Regulations 2012, NHSBT will be responsible for ensuring that the transplanting surgeon receives details of donor and organ characterisation prior to the implantation. This should be in electronic form; only when this is not possible should this be in written form. The transplanting surgeon should ensure that the details are reviewed prior to operating and the review noted in the clinical records. It is the responsibility of the Specialist Nurse in Organ Donation (SNOD) to obtain and accurately transmit all relevant available information.
3. It is the responsibility of the senior supervising / operating retrieval and implanting surgeons to follow up any anomalies or relevant queries with either the Specialist Nurse or the clinical staff who cared for the donor.
4. It is the responsibility of the senior supervising implanting surgeon to decide whether to accept the offered organ. The surgeon is encouraged to seek the views of colleagues who are aware of the condition of the potential recipient and record the outcomes of such discussions in the clinical records. All transplants carry risk, and the risk will depend on the characteristics of the donor, the organ and the recipient.
5. There are many local, national and international guidelines outlining risk assessment of organs from deceased donors. It is recommended that clinicians use those guidelines from SaBTO as the prime source of guidance, noting that these should be considered in light of any new developments that have occurred since the guidelines were issued.
6. The surgeon should be aware of current guidelines for accepting or refusing a graft but has the responsibility for deciding not to follow these where that is in the patient's best interest. In that case, the decision and reasons must be recorded.
7. The implanting surgeon has the responsibility for ensuring that the patient has been fully informed about the risks of transplantation, including donor-related conditions that represent a higher-than-average risk, and that the patient has given the appropriate informed consent. NHSBT and BTS have published guidelines to assist with patient consent for transplantation.
8. If the retrieval or implanting surgeon or any other clinician becomes aware of any donor-associated factor that could impact the health and safety of the other recipients of organs or tissues from that donor, the surgeon must inform the NHSBT Hub Operations immediately and submit an incident report to NHSBT within 24 hours via: <https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx>

## Introduction

As with any health intervention, solid organ transplantation is associated with risk of an adverse outcome and this risk has to be balanced against the anticipated benefit. The risk includes that associated with the organ itself, such as transmission of disease, infection, malignancy, metabolic and immune diseases, as well as poor or non-function of the organ following transplantation. In addition, donors are becoming older and more overweight and have additional co-morbidities, factors which potentially increase the risk to the recipient. Although screening of the donor and inspection of the organ prior to transplantation may reduce these risks, they cannot be abolished. Some organs are associated with higher risk and have been termed 'extended criteria', 'marginal' and 'high risk' grafts. None of these terms is ideal so these organs are here termed 'higher risk'. Some risks may be recognised at the time of donation, but others are unpredictable, and yet others are dependent on the interaction between donor and recipient. In deciding whether to accept or decline the offer for an individual recipient, the clinician should consider all aspects of the donor and the organ as well as the characteristics of the recipient.

Thus, the clinicians have to make the difficult decision whether to accept or decline an offered organ, with the risk that the potential recipient may become too sick or die before another, more suitable organ is available. The risks of death without transplantation will depend on the health of the potential recipient and is usually difficult to predict other factors that will affect the risk may include recipient's height, weight, blood group, tissue type, co-morbidities, sensitisation and any restrictions that the recipient might impose (such as not wishing to receive a lung from a donor who has smoked, or a split liver).

As outlined in the NHSBT/BTS Guidelines for consent for solid organ transplantation in adults (POL191), <https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/> the potential organ recipient should be informed about the risks associated with solid organs and asked to identify those donor characteristics that are not acceptable; this should be done, where appropriate, at the time of listing. When higher risk organs are being considered, **at the time of the offer** where practical and appropriate, the clinicians should discuss the use of the organ with the potential recipient and document the discussions and consent. It is good practice to ensure the potential recipient's family is aware of the additional risk.

## 1. Purpose of document

The purpose of the document is to outline the responsibilities of the clinician in deciding whether to accept or decline an offered organ for transplantation whilst working within the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (OQSR).

## 2. Responsibilities of clinicians

### 2.1. The Specialist Nurse in Organ Donation (SNOD)

Whilst working under NHSBT licence under the OQSR (2012) the SNOD is responsible for obtaining clinical and other information relevant to the possibility of donation and this is covered in the NHSBT MPD (Management Process Description, available from NHSBT), and for passing all of this information to the Recipient Point of Contact (RPoC). Where information is not available at the time or is missing, this should be made clear. All information should be recorded on to DonorPath and therefore visible to recipient centres via EOS (the Electronic Offering System) at the time of the offer. In exceptional circumstances, where transmission via EOS is not possible and information is transmitted verbally, then the SNOD should record the conversation using the NHSBT voice recording procedure, including all relevant information given to the RPoC and confirm in writing or electronically as soon as practicable. Any new information coming to light following acceptance of the organ that has a potential impact on the selection and management of the recipient (such as CMV or HTLV status, findings requiring histopathology assessment or significant medical history (past or present)) must be passed directly to the accepting centres' RPoC as soon as possible and in addition be recorded on DonorPath and reported to the NHSBT Hub Operations.

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## 2.2. The National Organ Retrieval Service (NORS) Team

The NORS Team should also review the donor's medical records once death has been declared and consent/authorisation for donation given. If the NORS Team obtains additional information that was not recorded by the SNOD, then the Team has an obligation to ensure that such information is made available to the recipient team; this will normally be done by the SNOD. Other responsibilities of the NORS Team are given in the National Organ Retrieval Standards (MPD1043) NORS Standards <https://www.odt.nhs.uk/retrieval/policies-and-nors-reports/>

## 2.3. The surgeon responsible for implantation of the donated organ

- 2.3.1. It is the ultimate responsibility of the lead surgeon doing or supervising the transplant to decide whether to transplant the organ into a given individual. In many cases, the surgeon accepting the organ may not be the surgeon responsible for the surgery so there should be close collaboration between the accepting and implanting surgeon. The accepting surgeon and the surgeon responsible for implanting the organ should review EOS (Core Donor Data Form CDDF) and the Medical and Social History Questionnaire Form (MaSH), both forms available through EOS. It is recommended that a reminder to check the CDDF and the MaSH form should be included on the WHO checklist used for all transplant operations.

The surgeon is encouraged to seek the advice of other clinicians who are aware of the clinical condition of the potential recipient. Where the organ is associated with higher risk, it is recommended that the surgeon seek advice from expert colleagues and that the discussion and rationale is recorded in the clinical records. The potential recipient should also be informed of any higher risk organ and his consent obtained; such discussions should be documented contemporaneously in the patient record.

2.3.2. Relevant information

The responsible surgeon should ensure that s/he has all the relevant information about both the donor and the recipient including any restrictions that the recipient may impose. Where the surgeon feels additional information is required before reaching a decision, then s/he should request this information from the SNOD and/or the clinical team looking after the potential recipient.

It is recognised that, because of the inevitable time constraints, not all necessary information will be available at the time of making the decision to use an organ. Where important information is not available, this should be recorded. This situation is more likely to occur in cases where donation occurs after circulatory death. In such cases, the surgeon must make a decision in the best interests of the patient.

2.3.3. Current guidelines

There are several sets of guidelines to help the implanting surgeon make an informed decision. These include the guidelines published by the Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) and those from professional societies. The surgeon must act in the best interest of the recipient by balancing the risks and benefits of using that organ with the consequences of declining and so waiting for another, lower risk organ to be offered.

2.3.4. Higher risk organs

Organs from some donors are associated with a greater risk than is generally accepted (e.g. history of cancer, undiagnosed infection); where such organs are used, the reasons for their use should be documented and the surgeon should ensure that there is appropriate consent by the recipient.

2.3.5. Use of organs contrary to current guidance

- 2.3.5.1. It is recognised that to use organs contrary to current guidance may, in some circumstances, be in the recipient's best interest in improving the length or quality of life or both and so such a course of action may represent good practice.
- 2.3.5.2. Where a surgeon decides to use organs that are contrary to published advice, the surgeon must ensure that such an approach has the recipient's informed and documented consent (see Section 2.4) inclusive of documenting on patient's electronic record where appropriate.
- 2.3.5.3. The reasons for the decision should be recorded in the patient's medical records together with details of any discussions that may have taken place.

## 2.4. Patient consent

Informed patient consent is necessary for any intervention and NHSBT and BTS have published guidelines to assist with patient consent for transplantation. It is noted that consent should normally be obtained at listing and confirmed prior to transplantation.

The surgeon must ensure that there is properly informed consent for the procedure and, where a higher risk organ is being considered, the potential recipient is aware of this and has given informed consent and, where appropriate, has the opportunity to decline its use.

## 2.5. All clinicians

If, during the course of the preparation or implantation of the organ, or during the follow-up of the patient, the clinicians become aware of any condition that might impact on recipients of other organs from the same donor (such as donor-derived cancer or infection), the clinician must inform NHSBT Hub Operations immediately by telephone (0117 975 7580) and follow this up with an incident report (<https://safe.nhsbt.nhs.uk/IncidentSubmission/Pages/IncidentSubmissionForm.aspx> via the NHSBT on-line reporting system) within 24 hours so that NHSBT can inform the relevant clinicians caring for patients at other centres to take appropriate action. Hub Operations Organ Allocation Specialists (OAS) are not clinically trained, therefore the reporting centre may be asked by the OAS to discuss the clinical aspects with a Specialist Nurse Organ Donation in line with NHSBT procedures, the clinician must indicate the nature of the risk to the recipients and the urgency of any action required. The OAS will make arrangements for this. NHSBT is responsible for reporting to the Competent Authority (Human Tissue Authority) those incidents that are classified under the OQSR (2012) as SAE or SAR (serious adverse events or serious adverse reactions).

## References

### Quality and Safety of Organs Intended for Transplantation

<https://content.hta.gov.uk/sites/default/files/2021-06/HTA%20The%20Quality%20and%20Safety%20of%20Organs%20Intended%20for%20Transplantation%20Documentary%20Framework%20April%202021.pdf>

### SaBTO guidance

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_121497](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121497)

### NHSBT/BTS guidance on Consent

<https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/>