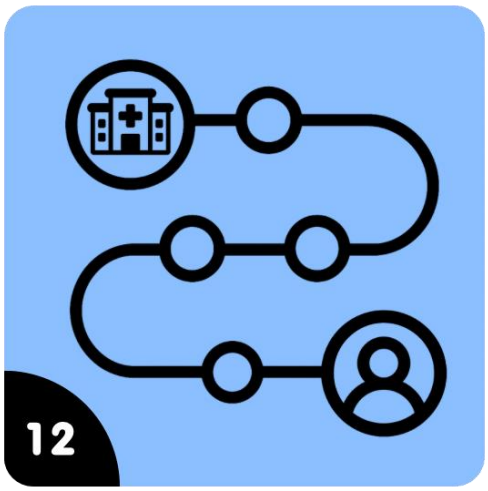

OTDT Manual 12: Recipient Centre National Operating Procedures in Deceased and Living Donation and Transplantation

Restrictions

This Manual is to be utilised by qualified and trained transplantation stakeholder. If the stakeholder is in training, this Manual is to be utilised under supervision. In the circumstance of requiring additional support or guidance please escalate to an appropriate colleague, such as a Lead Nurse (LN) or Organ Donation Leadership Team (ODLT).

Index *(hyperlinked)*

Summary of Changes

New additions

As part of the **OTDT Manuals project** - POL278, POL279, POL280, POL281, POL282 and POL283 have been fully integrated together into the host document (POL278 v2)
The aim is to support the users in navigation and context of process, while reducing duplication.

Further process/document changes:

- Donor record being available on TransplantPath
- Document section titles and contents list to help navigation
- Coroner/Procurator Fiscal consent is available under 'Consents' tab in TransplantPath
- Signing label attached to organ box upon receipt of an organ
- The word manual(s) is used instead of previous Policy / POL reference
- UKLDSS changed to UKLKSS
- SN-OD Team Manager / Regional Managers changed to Lead Nurse and Regional Head of Nursing, and definition added
- Reference to use of 10-degree refrigerator for lung transplantation
    - Addition of **Avoid extreme temperatures** when identifying and labelling an organ transport box

Removals Summary

- References to 'Core Donor Data Form and the Medical and Social History Form (MaSH)'
- References to POL279, POL280, POL281, POL282 and POL283 removed as they are now sections of this document (POL278).
- POL279, POL280, POL281, POL282 and POL283 will become obsolete on the effective date of this document (POL278

Introduction

The purpose of this manual is to define the national operating procedures that ensure the quality, safety, and traceability of organs intended for transplantation in both deceased and living donation. These procedures are designed to uphold patient safety, regulatory compliance, and best clinical practice across all stages of the donation and transplantation pathway.

1. **Donor and Organ Characterisation**
   Accurate and complete donor and organ characterisation is essential to safeguard transplant recipients and optimise organ allocation. This process enables recipient centres to identify and document any risks associated with organ use. The implanting surgeon holds ultimate responsibility for deciding whether to proceed with transplantation, based on a thorough review of all available information and a documented risk-benefit analysis.

2. **Verification of Identity, Consent, and Information**
   To minimise risk and uphold patient safety, the retrieving surgeon must confirm that all required donor and organ information is available prior to retrieval and identify any additional data needed. Similarly, the implanting surgeon must verify receipt of all relevant information before transplantation. The decision to use an organ remains the responsibility of the implanting surgeon, guided by a comprehensive risk-benefit assessment.

3. **Packaging, Labelling, and Transport of Organs**
   Maintaining organ integrity during transport is critical. Stringent requirements govern the packaging, labelling, and timely transportation of organs and accompanying blood/tissue samples. These measures safeguard transplant recipients, ensure traceability, and minimise potential risks throughout the transfer process

4. **Management of Procurement Materials and Equipment**
   All procurement materials and equipment that could impact organ quality and safety must comply with The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended), as well as relevant national and international standards for sterilisation and device management. This ensures that instruments and devices used during retrieval and transplantation meet regulatory and safety requirements.

5. **Medical Activities and Professional Competence**
   Healthcare personnel involved in organ donation and transplantation must be suitably qualified, trained, and competent. Specific medical activities: such as organ perfusion, packaging, and surgical procedures must be performed under the advice and guidance of a Registered Medical Practitioner (RMP), who retains overall responsibility for these activities.

6. **Data Transfer, Storage, and Traceability**
   To ensure full traceability across all stages of donation and transplantation, data: including donor and organ characterisation information, consent records, and perfusion details must be securely stored for 30 years. Strict confidentiality and data protection measures must be applied during transfer and storage, in compliance with regulatory requirements.

Patient Safety information:

Incident Reporting - An incident may occur within the chain of organ donation and transplantation for which there is a legal requirement to report under the Regulations. Additionally, an incident may occur for which we may benefit from organisational or national learning. These incidents should be reported to the ODT Directorate of NHSBT using the following link:
https://safe.nhsbt.nhs.uk/IncidentSubmission

Responsibilities (A-Z)

This manual is available to download from the NHSBT ODT Clinical website at www.odt.nhs.uk. Transplant Units may:

- Adopt the manual fully
- Adopt the manual with local adaptation
- Write their own procedural documents

If the manual is not fully adopted, Transplant Units must ensure that local procedures are compliant with the requirements of The Quality and Safety of Organs Intended for Transplantation Regulations and in accordance with the regulatory framework of the HTA: *The Quality and Safety of Human Organs Intended for Transplantation - a documentary framework.*

Accountability for the manual and its implementation will lie with each individual Transplant Unit. Transplant Units will be responsible for:

- Implementation of the manual according to local Trust/Board policy
- Document review according to local Trust/Board policy, and in response to developments in organ donation and transplantation practice, or changes in national policy or guidance
- Document control
- Staff training

Healthcare professionals who undertake activities related to management of procurement materials and equipment are responsible for working according to this procedure. This will include the:

- **Implanting Surgeon (living and deceased donation and transplantation) -** To ensure they have received and verified all relevant information obtained during donor and organ assessment to enable a decision on the safety and integrity of a donor organ before proceeding to transplantation. To ensure that the information is sufficient to permit characterisation of the donor and donated organ before the organ is used for transplantation. To ensure perfusion solution name and batch number(s) are recorded if organ is re-perfused following retrieval. To ensure HTA B Form is completed and returned to NHSBT within 7 days following transplantation of an organ, or if received organ is used for research or is disposed of.

- **Living Donor Coordinator (LDC) -** To undertake a thorough assessment of the potential donor to ensure an accurate medical, family and social history, in conjunction with Registered Medical Practitioners (RMPs) within the transplant medical team.

- **NHSBT Hub Operations -** To communicate donor information provided by the Specialist Nurse – Organ Donation (SN-OD) to the Recipient Centre Point of Contact (RCPoC).

- **Non-medical healthcare personnel** - To undertake medical activities in accordance with national and local organisational policy and procedures, and adhering to their professional codes of conduct. To seek advice and guidance as required.

- **Organ Preservation Practitioner (OPP) -** A trained practitioner who is responsible for performing preservation, perfusion and packing of organs.

- **Recipient Centre Point of Contact (RCPoC) -** To communicate information provided by the SN-OD to the implanting surgeon for a final decision to be made on accepting an organ for transplant. To communicate requests for further information from the implanting surgeon to the SN-OD or retrieving surgeons.

- **Registered Medical Practitioner** - To provide advice and guidance when required on specific medical activities.

- **Retrieval Surgeon (deceased donor) –** To ensure relevant NHSBT organ specific forms (HTA A Forms) are completed. To authorise relevant NHSBT organ specific forms (HTA A Forms).

- **Retrieval Surgeon (Living Donor) –**
    - To ensure relevant NHSBT living donor assessment pre and post-operative form is completed.
    - To sign relevant NHSBT living donor assessment pre and post-operative form.

- **Retrieving Surgeon (Deceased Donor) –**
    - To review and verify the information collated during donor assessment and to ensure relevant investigations have been performed. To undertake peri-operative assessment of the donor and donated organ/s.
    - To ensure the RCPoC and implanting surgeon are notified if an organ appears sub-optimal, or if any damage or unexpected abnormality is encountered which might compromise the function or safe use of an organ.
    - To ensure relevant NHSBT organ specific forms (HTA A Forms) are completed. To authorise relevant NHSBT organ specific forms (HTA A Forms).

- **Scrub Practitioner -** A trained theatre practitioner who is capable of providing expert assistance to the NORS surgical team at the table

- **Specialist Nurse – Organ Donation (SN-OD)** - To obtain and document information required for donor and organ characterisation. To seek advice and guidance from the retrieving or implanting surgeon, if required. To communicate all information to the RCPoC, NHSBT Hub Operations or the implanting surgeon.

- **Transplant Unit Personnel –** To ensure procedures are in place to record transportation details (to include date and time).

1. Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation

Section Contents - Hyperlinked

Section Purpose

The purpose of this section is to detail the information required to permit the characterisation of organ donors and donated organs before an organ is used for transplantation.
Text in this section which is underlined is a mandatory requirement under
The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

1.1. Introduction

Information from a potential donor's medical, family and social history, physical examination and complementary tests should be collected for the adequate characterisation of the organ and the donor. To obtain an accurate, reliable and objective history, interviews must be performed with the living donor or, where appropriate, with the relatives of the deceased donor, during which the potential risks and consequences of donation and transplantation are explained.

1.2. Information required for the characterisation of organs and donors

1.2.1. Before the decision is made to use an organ for transplantation, information must be available to permit characterisation of the organ donor and donated organ. Characterisation enables the implanting surgeon to assess the suitability of the donor and organ, to minimise the risk of harm to the transplant recipient.

1.2.2. The minimum mandatory information required for donor and organ characterisation is defined as the **Minimum Data Set** and **must be collected for all donors.**

1.2.3. The **Minimum Data Set** is specified in Part A of Appendix 1 to The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

1.2.4. In circumstances where this information is not available, the transplant medical team may still consider using an organ for transplantation. The decision to do so must consider the benefit to the intended recipient of the donated organ, versus the risks posed by the lack of information available. The implanting surgeon must document in the recipient's medical records:

- the decision
  and
- the risk-benefit analysis undertaken.

1.2.5. Other information that may be required for donor and organ characterisation is defined as the **Complementary Data Set.**

- The **Complementary Data Set** is specified in The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

1.2.6. Information in the Complementary Data Set **must be collected when it is considered necessary to permit adequate characterisation of a particular donor and donated organ.**

1.2.7. The transplant medical team is responsible for deciding if this information is required.

1.2.8. The decision to collect this information will consider the availability of the information, and the individual circumstances of the donor and the potential recipient of the donated organ.

1.2.9. The decision to use an organ for transplantation should consider:

- The absolute contraindications to organ donation specified in **POL188** *Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation*, and other relevant UK guidelines and standards documents (e.g. The British Transplantation Society Guidelines for Living Donor Kidney Transplantation (March 2018).
- The guidance issued by SaBTO on the use of organs from donors with infections or tumours.
- NHSBT Patient Selection and Allocation Policies.

1.2.10. To ensure quality, safety and reliability, all tests used for donor and organ characterisation must be carried out by appropriately accredited laboratories.

1.3. Sources of information for donor and organ characterisation

1.3.1. Information required for the characterisation of donors and donated organs will be collected by the SN-OD in deceased donation and by the LDC in living donation.

1.3.2. In **deceased** donation, the SN-OD will:

a) Undertake a thorough assessment of the potential donor to ensure an accurate medical, behavioural and travel history is available. Sources of information may include.
- Medical records from the current admission.
- Medical records from previous admissions where available.
- Information from the General Practitioner.
- Information from other specialists e.g. oncologists.
- Information from the potential donor's family including information regarding medical, behavioural, travel history.

b) Collate the results of relevant diagnostic tests including.
- Blood tests
- Blood group
- Microbiology
- Imaging/cardiology
- Screening for infections

1.3.3. Undertake a physical examination of the potential donor, and facilitate any further examination or assessments required, to identify factors that could have an impact on the quality and safety of organs for transplant.

1.3.4. In **living donation**, the LDC, in conjunction with Registered Medical Practitioners (RMPs) within the transplant medical team, will undertake a thorough assessment of the potential donor, including a physical and psychological evaluation, to ensure an accurate medical, family and social history. This assessment must be consistent with principles of best practice as specified in national and local standards, guidelines and policies (e.g. The British Transplantation Society Guidelines for Living Donor Kidney Transplantation (March 2018)

1.3.5. In **deceased and living donation**, the retrieving surgeon must review the information collated during the assessment of the potential donor, before retrieval, and ensure that factors that could affect the quality and safety of organs for transplantation have been identified and appropriately investigated.

1.3.6. The retrieving surgeon may discuss directly with the implanting surgeon any implications for the intended recipient of the donated organ.

1.4. Peri-operative assessment of donor and organ characterisation

1.4.1. Principles of best practice, as specified in national and local standards, guidelines and policies, should be applied to the peri-operative assessment of donor and organ characterisation (e.g. the National Standard for Organ Retrieval from Deceased Donors (NORS standard - **MPD1043**), The British Transplantation Society Guidelines for Living Donor Kidney Transplantation (March 2018)).

1.4.2. The retrieving surgeon is responsible for:

- Peri-operative assessment of the donor and donated organ/s.
- Taking all reasonable steps to assess for evidence of previously unidentified co-morbid disease in the donor (particularly malignancy) that could affect the quality and safety of the donated organ/s.
- Identifying any disease process that could affect the suitability of an organ for transplant and ensuring that it is discussed immediately with the implanting surgeon.
- Ensuring the NHSBT Hub Operations is informed immediately if malignancy, or other relevant finding, is identified in an organ from a deceased donor, so that the information can be relayed to all relevant recipient teams.
- Ensuring the RCPoC and implanting surgeon are notified immediately if an organ appears sub-optimal, or if any damage or unexpected abnormality is encountered which might compromise the function or safe use of that organ
- Signing the completed organ specific forms (**FRM4194/4147/4121/4122**), recording which organs have been removed from the body, all abnormalities/anomalies, organ damage, sub-optimal perfusion or donor instability during retrieval.
- Documenting full details of the donor operation in the donor's medical record, including:
    - Which organs and tissues have been removed from the body
    - Any abnormalities/injuries noted

1.4.3. The retrieving surgeon must sign the medical records entry and print their name and the name of the retrieval centre with a contact telephone number.

1.5. Transmission of information

Deceased donation

1.5.1. The SN-OD will record donor characterisation information on DonorPath which in turn will populate the donor record on TransplantPath, for which users must have valid login credentials. It is vital that all sections of the donor record on TransplantPath are reviewed in their entirety by the recipient transplant teams, particularly when accepting an organ offer.

1.5.2. Hard copies of all results will be collated where possible.

1.5.3. The SN-OD will communicate any relevant information to the RCPoC, or implanting surgeon, verbally, via TransplantPath or via the NHSBT Hub Operations.

1.5.4. Once an organ has been offered to a recipient centre, any further changes made to DonorPath must be communicated verbally as well as electronically to the RCPoC.

1.5.5. Information that cannot be entered onto TransplantPath will be emailed to recipient centres via secure email where possible. The recipient centres will be notified that information that cannot be entered onto TransplantPath and will be forwarded where possible by either the SN-OD or Hub Operations.

1.5.6. Images and media files required to support decision making of organ acceptance will be available via TransplantPath.

Living donation

1.5.7. For directed donations, information on donor and organ characterisation will be held within the donating and/or recipient centres and transmitted to NHSBT Data Executive within one month of the date of donation.

1.5.8. In the UKLKSS, information on donor and organ characterisation is transmitted to NHSBT at the time of recipient and donor registration. Subsequent to matching, LDCs in donating and recipient hospitals will exchange relevant donor and recipient information to inform the preparation and scheduling of the donation and implantation surgery.

1.6. Assessment of donor and organ characterisation at the recipient centre

1.6.1. Principles of best practice as specified in national and local standards, guidelines and policies should be applied to the assessment of donor and organ characterisation at the recipient centre (e.g. NORS Standards, The British Transplantation Society Guidelines for Living Donor Kidney Transplantation March 2018, SaBTO).

1.6.2. The implanting surgeon is responsible for:

- Checking the integrity of the organ and the suitability of the organ for the recipient.
- Ensuring that they have received all relevant information about the donor and donated organ to enable a decision to be made on its suitability for implantation. In deceased donation the surgeon should review the full donor record prior to implantation via TransplantPath
- Ensuring that identity details on all documentation and tissue samples (where relevant) accompanying the organ are checked and correlate with those given to the RCPoC. As a minimum, this will include 3 unique identifiers:

- In deceased donation: donor ODT number, donor date of birth donor and NHS/CHI/NIHSC number
- In living donation: donor name, date of birth, hospital number/CHI number and ODT Recipient number.

- Checking that the organ has been transported appropriately to maintain quality and safety, and within an acceptable ischaemic time.
- Ensuring that the Organ Specific Form (**FRM4194/4147/4121/4122**) and, in deceased donation, the witnessed blood group form accompanying the organ in the transport box, are reviewed.

1.6.3. Recipient centres must immediately report to Hub Operations at NHSBT any abnormality found which contributes directly to donor and organ characterisation and complete an online NHSBT Incident Submission Form https://safe.nhsbt.nhs.uk/IncidentSubmission

1.7. Storing data on organ/donor characterisation

1.7.1. Information on donor and organ characterisation, including any risk-benefit analyses undertaken, **must be stored for 30 years** (Transfer and Storage of Donor and Organ Characterisation Information and Storage oof Traceability Data).

2. Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation and Transplantation

Section Contents - Hyperlinked

Section Purpose

The purpose of this section is to outline the responsibilities of:

- The retrieving surgeon in the verification of patient identity, consent/authorisation and organ/donor characterisation prior to organ retrieval.
- The implanting surgeon in the verification of information received on a donated organ and donor characterisation to enable them to make an informed decision on the safety and suitability of an organ for transplantation.

Text in this section which is underlined is a mandatory requirement under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

2.1. Introduction

2.1.1. In deceased and living donation and transplantation, a thorough assessment must be performed to enable characterisation of the donor and donated organ.

2.1.2. In deceased donation, the SN-OD is responsible for collating all relevant donor information and communicating with the RCPoC and NHSBT Hub Operations. Any findings that could affect the integrity and safety of the organ for transplant must be communicated to the RCPoC. The RCPoC is responsible for communicating information to the implanting surgeon.

2.1.3. Before retrieval begins, the retrieving surgeon must verify that all required information is available and identify any further information that may be required. There may be occasions when the retrieving surgeon discusses any abnormal findings directly with the implanting surgeon.

2.1.4. In living donation, the LDC is responsible for collating all relevant donor information and communicating with the donor and recipient medical teams, including the retrieving and implanting surgeons. In UKLKSS, the LDC (donating centre) is responsible for communicating with NHSBT to register special considerations that may impact on the integrity and suitability of the donated organ prior to kidney donor matching runs. The LDC (donating centre) and the NHSBT Living Donor

Scheme Co-ordinator communicate this information to the LDC/RCPoC in the recipient centre. At time of surgery, the LDC/retrieving surgeon in the donating centre will liaise with the LDC/RCPoC/implanting surgeon to discuss additional relevant information that could affect the integrity and safety of the donated organ.

2.1.5. Before proceeding to transplantation, the implanting surgeon must ensure that they have received all relevant information to permit donor and organ characterisation.

2.2. Verification of donor identity prior to retrieval

DECEASED DONATION

2.2.1. Each retrieving surgeon is responsible for confirming donor identity prior to retrieval.

2.2.2. The deceased donor will have two name bands attached. As a minimum there will be three forms of identification: name, date of birth and NHS/CHI/NIHSC number.

2.2.3. Retrieving surgeons must ensure that donor identity details correlate with those recorded in the medical records, on the confirmation of death documentation, on the consent/authorisation documentation, and on any other documentation/investigation reports/results.

2.2.4. Verification that patient identity has been checked will be recorded on the Retrieval Checklist on DonorPath.

LIVING DONATION

2.2.5. The retrieving surgeon is responsible for confirming donor identity prior to retrieval.

2.2.6. The living donor will have two name bands and identification will be made according to local Trust/Board policy. There will be three forms of identification: name, date of birth and hospital/CHI number.

2.2.7. Retrieving surgeons must ensure that donor identity details correlate with those recorded in the donor's medical records, on the relevant operation consent, and on any other documentation/investigation reports/results.

2.2.8. Verification that donor identity has been checked must be recorded on the pre-operative checklist.

2.3. Verification of consent/authorisation for organ/tissue donation prior to retrieval - deceased donation

2.3.1. The SN-OD will have obtained consent/authorisation for organ donation during donor assessment.

2.3.2. Consent/authorisation will be documented on **FRM4281** (England, Wales and Northern Ireland) or **FRM1538** (Scotland).

2.3.3. The retrieving surgeon must verify that consent/authorisation for organ/tissue donation has been given.

2.3.4. The retrieving surgeon must also establish which organs/tissues are to be donated and for what purpose/s consent/authorisation has been given.

2.3.5. Verification that consent/authorisation for organ donation has been checked must be recorded on the Retrieval Checklist on DonorPath.

2.4. Verification of Coroner / Procurator Fiscal permission, or procurator fiscal consent, to organ donation - deceased donation

2.4.1. Where required, the retrieving surgeon must check that the Coroner/Procurator Fiscal has been informed.

2.4.2. The retrieving surgeon must check that the Coroner / Procurator Fiscal has no objections to organ donation proceeding, or that the Procurator Fiscal has given consent.

2.4.3. Coronial permission will be documented on DonorPath and will appear on TransplantPath under the 'Consents' tab (England, Northern Ireland and Wales).

2.4.4. Procurator Fiscal consent will be documented on Authorisation Form **FRM1538** (Scotland).

2.4.5. Verification of Coroner / Procurator Fiscal lack of objection, must be checked under the 'Consents' tab on TransplantPath.

2.5. Verification of consent for organ donation prior to retrieval - living donation

2.5.1. Surgical consent for living organ donation is a two-stage procedure according to surgical best practice (i.e. NHS Consent process). Written consent will be obtained by a suitably qualified member of the surgical team during living donor evaluation and documented in the donor's medical records.

2.5.2. Consent will also be obtained for NHSBT to hold information about the donor prior to donation.

2.5.3. Confirmation of donor preference regarding re-implantation, or reallocation of the donated organ (should it not be possible to implant it into the intended recipient), will be established and documented in the donor's medical records at the time of obtaining surgical consent, in accordance with Human Tissue Authority (HTA) requirements.

2.5.4. According to HTA requirements, the fully evaluated living donor will be Independently Assessed to ensure that consent can be given freely and voluntarily, and that there is no evidence of coercion or reward. Subject to these requirements, HTA approval to proceed with the donation is granted.

2.5.5. On admission for donor surgery, the implanting surgeon will confirm consent (Part 2), and that HTA approval has been obtained and is current. This will be documented in the donor's medical records.

2.6. Verification of donor characterisation prior to retrieval

2.6.1. Information required for the characterisation of donors and donated organs will be collected by the SN-OD in deceased donation, and by the LDC in living donation.

2.6.2. The responsibilities of verification of donor characterisation prior to retrieval in deceased donation can be found in the previous section – see here

2.6.3. Information will be recorded on DonorPath which will then populate the Core Donor Data form, and the Medical and Social History (MaSH) form.

2.6.4. As specified in the NORS Standard document **MPD1043**, it is the retrieving surgeon's responsibility to check the information specified in 'Verification of consent/authorisation for organ/tissue donation prior to retrieval - deceased donation' before proceeding to retrieval

2.6.5. This check of information will include cross reference to the hard copy blood group against the blood group entry on DonorPath

2.6.6. As specified in the NORS Standard document **MPD1043**, the retrieving surgeon must also check that brain stem death, or circulatory death, has been confirmed and documented in the donor's medical records.

2.6.7. Verification that all relevant donor information has been checked must be recorded on the Retrieval Checklist on DonorPath.

2.6.8. In **living donation**, the LDC, in conjunction with Registered Medical Practitioners (RMPs) within the transplant medical team, will undertake a thorough assessment, of the potential donor, including a physical and psychological evaluation, to ensure an accurate medical, family and social history. This assessment must be consistent with principles of best practice as specified in national and local standards, guidelines and policies (e.g. The British Transplantation Society Guidelines for Living Donor Kidney Transplantation March 2018, SaBTO).

2.6.9. This assessment will be documented in the donor's medical records.

2.6.10. In **deceased and living donation**, the retrieving surgeon must review the information collated during the assessment of the potential donor, before retrieval, and ensure that factors that could affect the quality and safety of organs for transplantation have been identified and appropriately investigated.

2.7. Perioperative assessment of donor and organ characterisation

2.7.1. Principles of best practice, as specified in national and local standards, guidelines and policies, should be applied to the peri-operative assessment of donor and organ characterisation (e.g. the NORS standards, The British Transplantation Society Guidelines for Living Donor Kidney Transplantation March 2018, SaBTO).

2.7.2. The responsibilities of the retrieving surgeon in perioperative assessment of donor and organ characterisation can be found in the previous section – see here

2.7.3. The retrieving surgeon must sign the medical records entry and print their name and the name of the retrieval centre with a contact telephone number.

2.8. Receipt of the donor organ at the recipient centre

2.8.1. The receipt of an organ at a recipient centre must be recorded. The responsible person receiving the organ must record the date and time of arrival, this must then be transcribed onto the HTA B form. It is recommended that the organ label attached to the organ box is signed with a date and time.

2.8.2. The responsible person receiving the organ must:

- Confirm the identity of the person delivering the organ. This should be done through proof of identification via a badge of the transport company, with photographic evidence of the transport personnel.

- Confirm the type of organ that is being delivered and its point of origin, and ensure that these details are consistent with those specified by NHSBT Hub Operations/RCPoC/donating hospital LDC.
- Check that the Organ box ID number/asset number (where available) on the organ box correlates with that given by NHSBT Hub Operations/RCPoC/donating hospital LDC.
- Check that the organ transport box is structurally intact and fastened securely (where possible).
- Remove the organ box sealing tape supporting the hinge mechanism.
- Ensure the exterior of the organ transport box is socially cleaned with universal surface disinfection wipes.

2.8.3. If using standard cold storage boxes, the level of ice in the organ transport box must be checked, and more ice added, if required, to ensure that the organ is completely covered.

2.8.4. The organ must remain in the transport box/system in a secure location at the recipient centre until it is transferred is into the operative field for implantation.

2.8.5. After removing the organ from the transport box, the ice should be emptied out and the box cleaned with a sterile wipe (or with warm water and 5.25% sodium hypochlorite to remove any stains) ensuring any remaining particles from the organ box sealing tape are removed. The box must be left to air dry before re-sealing.

2.8.6. In the case of kidney boxes, check the box inside and out for any damage, particularly any damage to the seal inside the lid. If any damage is noted, inform KidneyTransportBoxes@nhsbt.nhs.uk. Heart, lung and liver boxes are the property of individual Trusts so damage needs to be reported to the relevant hospital contact and should be returned to the NORS centre as soon as possible.

2.8.7. For traceability, records of organs arriving at a recipient centre must be stored for 30 year – see Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

2.9. Verification of donor and organ characterisation at the recipient centre

2.9.1. Principles of best practice, as specified in national and local standards, guidelines and policies, should be applied to the verification of donor and organ characterisation at the recipient centre (e.g. NORS Standards, The British Transplantation Society Guidelines for Living Donor Kidney Transplantation March 2018, SaBTO).

2.9.2. The implanting surgeon responsibilities of the retrieving surgeon in verification of donor and organ characterisation at the recipient centre can be found in the previous section – see here

2.9.3. Recipient centres must immediately report to Hub Operations at NHSBT any abnormality found which contributes directly to donor and organ characterisation.

3. Packaging, Labelling and Transport of Organs In Deceased and Living Donation and Transplantation

Section Contents - Hyperlinked

Section Purpose

The purpose of this procedure is to give guidance on the requirements for the packaging, labelling and transport of organs for use in transplantation. This includes packaging, labelling and transport of organs from:

- Deceased donors - organs received from donor hospitals that are unpacked and then need to be repacked before transportation to another recipient centre (e.g. organs that are reallocated, liver lobes from a liver that is split).
- Living donors - organs transported from the donating centre to the recipient centre.

Text in this section which is underlined is a mandatory requirement under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

3.1. Introduction

3.1.1. The competent retrieval surgeon or registered medical practitioner must ensure that organs are appropriately packaged and labelled and that any specimens required by recipient centres to support transplantation are also appropriately packaged and labelled to accompany the organs.

3.1.2. Organs must be prepared and packaged appropriately to maintain their integrity during transport. Organ transport boxes must be fit for purpose, maintaining the security and confidentiality of information contained in accompanying documentation. Organ transport boxes must be capable of maintaining preservation temperatures, and able to minimise the risk of contamination of the organ and the risk of infection to healthcare and transport personnel.

3.2. Packaging an organ for transport

3.2.1. Packaging an organ in preparation for transport is defined as a **medical activity**. This means that the activity must be performed **under the advice and guidance of a registered medical practitioner (RMP).** Further information available here.

3.2.2. Any practitioner undertaking responsibility for preparing and packaging an organ for transport must be appropriately trained in the role. The RMP must seek advice immediately in the event of a problem being identified.

3.2.3. Organs must be prepared for packaging in line with National Abdominal Organ Preservation Protocol and the Cardiothoracic Perfusion protocol within the current NORS Standards (MPD1043) available at https://www.odt.nhs.uk/retrieval/policies-and-nors-reports/

3.2.4. The organ may be transported in an organ box or transportable perfusion system. Transport of organs in transportable perfusion systems must be according to local policy.

3.2.5. The person packing the organ in the box for transport must ensure that:

- It is structurally intact
- It can be fastened securely, where possible, to prevent unauthorised or accidental opening
- It contains sufficient melting water ice to maintain the temperature and position of the organ during transit
- Any previous documentation, not related to the current donor or donated organ is removed and returned to Information Services at NHS Blood and Transplant.

3.2.6. NHSBT owns and procures the small organ boxes which accommodate pancreas, kidneys, heart for valves and tissues/vessels. NORS teams/transplant centres, own and procure the large organ boxes for accommodating lungs, liver, heart for transplant and visceral tissue. Small organ boxes must be sealed on both sides of the transport box using tamper proof organ box sealing tape, taking care to avoid the bar code sticker/asset number. Large organ boxes must also be sealed with tamper proof sealing tape when closed.

3.2.7. Before an organ is packed in the organ transport box, the following must be confirmed:

- Which organ is being handed over by the scrub practitioner/surgeon, there will be an organ specific colour coded label (if using sterile retrieval pack) or colour coded sling (if not using sterile retrieval pack). This will identify the organ type and laterality -Blue for Pancreas; Red for Right Kidney; Yellow for Left Kidney.
- That the organ has been surrounded by perfusion/preservation fluid and bagged according to the National Standards for Organ Retrieval from Deceased Donors (MPD1043).

3.2.8. A suite of colour coded organ identification labels are available for use with the large organ boxes. Purple for lungs, pink for heart for transplant in cold static storage as opposed to machine perfusion, green for liver. Orange labels will be used for organs involved in research. The appropriate box will need to be ticked on the label, to indicate which organ is inside.

3.2.9. The prepared and packaged organ must be packed immediately inside the organ transport box.

3.2.10. The following actions should be taken for all organs, and a 2-person check undertaken between the SN-OD and the OPP:

- The packed organ must be contained and covered by melting ice
- The box should be closed but not sealed until all required blood, tissue samples and documentation have been placed inside and are ready for transportation

3.2.11. Before dispatch and transportation, and where applicable, both small and large organ transport boxes must be sealed on both sides with tamper proof organ box sealing tape. The SN-OD should record the asset number on DonorPath. The OPP should record the large organ box name/number and destination on their own paperwork.

3.2.12. The SN-OD and OPP must agree the box is sealed sufficiently to secure contents safely before handing over for dispatch.

3.3. Labelling and packaging of tissue/blood samples to accompany an organ in deceased donation

3.3.1. All tissues and blood samples required to support transplantation of a donor organ must be labelled with the patient's name and 3 points of identification:

- ODT number
- Date of birth
- NHS/CHI/NIHSC number

3.3.2. Tissue samples must be placed into tissue sample containers filled with sterile saline in addition to identification labelling; each container will also be labelled with details of the specific tissue contained within it. Once all required tissue samples have been received, the containers should be stored within a sealable sample pouch and placed into the relevant organ transport box.

3.3.3. Blood vessels, if required, must be placed into appropriately labelled sterile tamper proof blood vessel containers filled with preservation/perfusion fluid. The containers must be kept sterile at all times. The blood vessels container should be placed into a sealable sample pouch and stored in the relevant organ transport box. The NHSBT vessels form (FRM6199) must be fully completed and accompany any blood vessels, along with an additional 2 clotted blood samples.

3.4. Identification and labelling of an organ transport box

3.4.1. The organ transport box must be clearly labelled and identified with any corresponding colour-coded transport label to show than an organ is being transported. The following must be visible on the box.

- Handle with Care"
- **Avoid extreme temperatures**
- "Organ in Transit"
- After deceased donation, the contact telephone number for NHSBT Hub Operations (+441179757580).
- The name of hospital where the retrieval took place
- Identification of which organ is inside the organ transport box
- Identification of the destination recipient centre, including the full address
- Specific instructions on the required transport conditions e.g. keep upright.

3.4.2. The transport box must be labelled using the appropriate colour coded organ box label.

3.5. Documentation to accompany an organ

3.5.1. The following documentation must accompany an organ and be placed inside the organ box. It must be separate from the organ and protected by an appropriate waterproof bag or the waterproof document wallet provided by NHSBT:

- Organ Specific HTA-A Form completed by the retrieval surgeon.
- Photocopy of the witnessed blood group form (deceased donation only).

3.5.2. Information on donor characterisation (deceased donor), and where necessary, photographs and/or video files to support decision making, will be available electronically via TransplantPath.

Information that cannot be entered electronically will have been communicated via the RCPoC by NHSBT Hub Operations, using secure email, or directly to the implanting surgeon.

3.5.3. In living donation (directed donations), information on donor and organ characterisation will be held within the donating and/or recipient centres and transmitted to NHSBT Data Executive within one month of the date of donation.

3.5.4. In the UKLKSS, information on donor and organ characterisation is transmitted to NHSBT at the time of recipient and donor registration. Subsequent to matching, LDCs in donating and recipient hospitals will exchange relevant donor and recipient information to inform the preparation and scheduling of the donation and implantation surgery.

3.6. Sealing the organ transport box

3.6.1. The organ transport box must be secured, where applicable, with tamper proof organ box sealing tape for both small and large organ boxes, to ensure that the box remains securely closed. Organ box ID/tag/asset numbers for each organ must be relayed to NHSBT Hub Operations to maintain traceability from the donating hospital to the recipient centre.

3.7. Arranging transport of an organ

3.7.1. The transport of organs must only be arranged through contracted transport provider organisations.

3.7.2. There must be a Service Level Agreement (SLA) with each transport provider organisation to ensure that the conditions for transport of an organ meet the requirements to maintain the integrity of the organ during transport to recipient centres.

3.7.3. Transport provider organisations must be able to demonstrate their ability to meet service requirements. This should include the ability to:

- Ensure a professional code of conduct
- Provide a timely response to transport requests
- Maintain appropriate conditions of transit
- Ensure timely delivery of organs to their destination
- Manage/report adverse events during transport
- Monitor the progress of a journey
- Provide vehicles fitted with mobile communication devices, and with routeing/GPS tracking facilities
- Ensure the relevant licences for all vehicles and drivers

3.7.4. There must be an identified person responsible for arranging transport of an organ.

3.7.5. The person arranging transport must agree transport timings with the RCPoC, taking into account the acceptable cold ischaemic time of the specific organ. This information must be communicated to the transport company.

3.8. Releasing an organ for transport

3.8.1. The person releasing an organ for transport must:

- Confirm the identity of the person collecting the organ. This should be done through proof of identification via a badge of the transport company, with photographic evidence of the transport personnel.
- Confirm the type of organ that is being dispatched, the intended destination and the required time of arrival.
- Check that the organ transport box is structurally intact and fastened securely.

3.8.2. The person releasing an organ for transport must record the date and time of handover to transport personnel, and sign, print and date the record.

3.8.3. For traceability, records of organs released for transport must be stored for 30 years - see Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

3.9. Receipt of the donor organ at the recipient centre

3.9.1. The receipt of the organ at a recipient centre must be recorded. The person receiving the organ must record the date and time of arrival, and sign, print and date the record. The person delivering the organ must sign, print and date the record.

3.9.2. The person receiving the organ must**:**

- Confirm the identity of the person delivering the organ. This should be done through proof of identification via a badge of the transport company, with photographic evidence of the transport personnel.
- Confirm the type of organ that is being delivered and its point of origin and ensure that these details are consistent with those specified by NHSBT Hub Operations/RCPoC/donating hospital LDC.
- Check that the Organ box ID/asset number (if attached) correlates with that given by NHSBT Hub Operations/RCPoC/donating hospital LDC.
- Check that the organ transport box is structurally intact and fastened securely
- Socially clean the exterior of the organ transport box with universal surface disinfection wipes.

3.9.3. In the case of cold organ storage, the level of ice in the organ transport box must be checked, and more ice added, if required, to ensure that the organ is completely covered.

3.9.4. The organ must remain in the transport box in a secure location at the recipient centre until it is transferred into the operative field for implantation. In the scenario of lung transplantation, a 10-degree refrigerator can be used for preservation purposes, in line with local policy.

3.9.5. After removing the organ from the transport box, the ice should be emptied out and the box cleaned with a sterile wipe (or with warm water and 5.25% sodium hypochlorite to remove any stains). The box must be left to air dry before re-sealing.

3.9.6. In the case of kidney boxes, check the box inside and out for any damage, particularly any damage to the seal inside the lid. If any damage is noted, inform KidneyTransportBoxes@nhsbt.nhs.uk. Heart, lung and liver boxes are the property of individual Trusts, so damage needs to be reported to the relevant hospital contact.

3.9.7. For traceability, records of organs arriving at a recipient centre must be stored for 30 years - see Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

4. Management of Procurement Material and Equipment in Deceased and Living Donation and Transplantation

Section Contents - Hyperlinked

Section Purpose

The purpose of this procedure is to provide information on the management of procurement materials and equipment to ensure the quality and safety of organs for transplantation is maintained.
Text in this section which is underlined is a mandatory requirement under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

4.1. Introduction

4.1.1. Organ retrieval must take place in an operating theatre in an NHS, or private, hospital, which is designed, constructed, maintained and operated in accordance with adequate standards and best medical practices.

4.1.2. During organ retrieval, good operating department practice must be followed as defined in national and local standards, guidelines and policies.

4.1.3. Material and equipment used in organ retrieval must meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618) where these apply.

4.1.4. Material and equipment used in organ retrieval must be subject to a validated cleaning and sterilisation procedure for removal of infectious agents when reusable instruments are used.

4.1.5. Records of organ perfusion fluid used to perfuse and preserve each organ must be stored for 30 years.

4.2. Medical devices

4.2.1. Medical Devices are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). Devices approved for marketing in Great Britain carry a CE marking and/or UKCA marking. Devices approved for marketing in Northern Ireland carry a CE marking. Meaning:

- the device meets the relevant regulatory requirements
- performs as intended
- complies with the necessary requirement covering safety and performance
- is acceptably safe

4.2.2. Many items of equipment used in procurement and transplantation activity are defined, for the purpose of regulation, as medical devices. This includes (but is not limited to):

- Blades

- Sutures
- Syringes and needles
- Surgical gloves
- Surgical instruments
- Dressings
- Infusion pumps
- Endotracheal tubes
- Intravenous administration sets
- Endoscopes
- Organ perfusion and preservation fluid

4.2.3. Medical devices used in procurement and transplantation activities must:

- Be approved for use in the UK
- Be purchased according to local Trust/Board policy
- Be used, maintained and serviced in accordance with manufacturers' instructions and local Trust/Board procedures to ensure the continued safe operation of the device
- Be used for their intended purpose
- Be free from signs of wear, damage or faults
- If approved for single use, be used once and disposed of after the procedure
- Be within the expiry or use-by date (where applicable) and with packaging (if present) intact

4.2.4. For new medical devices that are under development, approval for use must be obtained.

- From the Medical Director of NHSBT
- According to local Trust/Board policy and procedures
- From the appropriate research ethics committee, if in the context of a clinical trial

The Research Operational Feasibility Group (ROFG) secretariat should be advised of new medical devices under development. The ROFG secretariat will advise as to whether the medical device will need ROFG approval for use or if awareness of use of the medical device is sufficient. The ROFG secretariat can be contacted via ODTresearch@nhsbt.nhs.uk

4.2.5. Information on the use of non-CE marked/ non-UKCA marked medical devices can be obtained from the MHRA (www.mhra.gov.uk).

4.2.6. Healthcare personnel using a medical device must be appropriately trained and competent in its use.

4.2.7. Before use, appropriate safety checks must be carried out (e.g. electrical equipment must be registered and safety tested according to local Trust/Board policy).

4.2.8. Where applicable, a schedule of cleaning and maintenance must be in operation.

4.2.9. Where there is concern about the safe functioning of a medical device, the device must not be used. Concerns about the safe functioning of a medical device must be reported to via local Trust/Board incident reporting mechanisms. By law, any important defect must be reported to the MHRA.

4.2.10. Medical devices should be used in accordance with the manufacturer's instructions. If a device is used in any other way it is considered off-label use. There may be circumstances where there is no option but to use a device off label. In these circumstances the user must balance the risks and

benefits to the patient taking into account MHRA guidance on 'Off label use of a medical device', which includes:

- carrying out a risk assessment and documenting it
- considering the ethical and legal implications
- implementing suitable precautions to minimise the risk
- reviewing the risk assessment at suitable periods
- getting approval from MHRA for exceptional use of non-complying devices (if necessary)

4.2.11. Patients must be informed during the consent procedure, and a note made on their records, that a medical device off-label will be used.

4.3. Reusable medical devices

4.3.1. Reusable medical devices (e.g. surgical instruments, bronchoscopes) must undergo decontamination to ensure the items are safe for further use on patients, and for handling by staff.

4.3.2. Decontamination must be carried out in accordance with Department of Health guidance and local Trust/Board policy and procedures.

4.3.3. Surgical instrument trays and individually packed instruments must have identification labels that confirm they have undergone decontamination.

4.3.4. At the end of the retrieval procedure:

- Damaged or faulty medical devices must be identified, and the appropriate procedure followed to ensure their repair or replacement
- All reusable medical devices must be packaged appropriately to prevent the risk of injury or infection to healthcare or transport personnel
- Medical devices intended for single use only must be disposed of after use according to local policy

4.4. Perioperative management of procurement materials and equipment

4.4.1. Principles of best practice, as specified in national and local standards, guidelines and policies, should be applied to the peri-operative management of procurement materials and equipment.

4.4.2. Members of the retrieval team are responsible for ensuring that all aspects of the retrieval operation are conducted in accordance with strict infection control procedures.

4.4.3. Before incision, the surgical pause must be observed to ensure that all safety checks have been completed to confirm donor identity, consent/authorisation for organ donation, and the organs to be retrieved. All members of the team must confirm that they are prepared and ready to start the procedure.

4.4.4. The Scrub Practitioner is responsible for:

- Ensuring that all equipment entering the operative field is sterile.
- In conjunction with the retrieving surgeon and the OPP/SN-OD/LDC, ensuring that organs are packaged correctly, to maintain their integrity and safety until implantation (see Section 3).
- Checking identification labels on surgical instruments to confirm that they have undergone the appropriate decontamination procedure.

- Identifying and replacing damaged or faulty instruments before the retrieval procedure begins.
- Ensuring that items with the potential to be left inside the body are accounted for, at all times, by performing swab, needle and instrument checks, at the beginning and end of the retrieval procedure, and at other times as appropriate.
- Repackaging reusable equipment safely to prevent injury/risk of infection to transport or healthcare personnel.
- Attaching identification labels from instrument trays to the donor's theatre care plan.
- Recording details of the identification labels on instrument trays in the theatre register and care plan.
- Ensuring that reusable equipment is sent for decontamination according to local Trust/Board procedure, noting damaged or faulty instruments that need repair or replacement.
- Ensuring safe disposal of single-use items.

4.5. Perfusion fluids

4.5.1. Organ perfusion is defined as a **medical activity**. This means that the activity must be performed **under the advice and guidance of a registered medical practitioner (RMP)**. Further information is available here.

4.5.2. In practice, this activity is frequently undertaken by other non-medically qualified healthcare professionals. In deceased donation, it will be performed by the Organ Preservation Practitioner with the retrieving surgeon present in theatre. In living donation, the LDC, Scrub Practitioner or Organ Preservation Practitioner may take on this role.

4.5.3. The responsibility for organ perfusion must be agreed before the retrieval procedure begins.

4.5.4. In deceased and living donation, details of perfusion fluids used to perfuse each organ must be recorded on the relevant HTA – A form, including details of the perfusion fluid used in packaging an organ in preparation for transport to the implanting centre. The information to be recorded will include:

- Perfusion fluid type
- Batch number

4.5.5. Additionally, there are organ specific details that need to be recorded on the HTA A forms:

Liver only	Cardiothoracic only
In situ (Portal vein, Aorta) • Fluid type • Volume • Quality (Good/Fair/Poor/Patchy)	**Heart** • Fluid type • Volume • Perfusion method
Benchwork (Hepatic artery, bile duct, portal vein) • Fluid type • Volume • Quality (Good/Fair/Poor/Patchy)	**Lungs** • Fluid type • Volume • Perfusion method
	Antegrade pulmonary artery flush perfusion • Yes/No • Volume
	Retrograde pulmonary venous flush perfusion • Yes/No • Volume

4.5.6. For traceability, records of perfusion fluids used to perfuse each organ must be recorded using the appropriate HTA A & B forms which must be returned to NHSBT who will store the data for 30 years - see Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

4.5.7. The member of the team responsible for recording the perfusion fluids details must be agreed before the retrieval procedure begins

4.6. Medicines and intravenous fluids

4.6.1. Medicines and intravenous fluids that are administered during organ retrieval should be licensed for use in the UK.

4.6.2. Principles of best practice in medicines management must be applied to the storage, reconstitution and administration of all medicines and intravenous fluids.

4.6.3. If unlicensed medicines or intravenous fluids are to be used, approval must be sought:
- From the Medical Director of NHSBT
- According to local Trust/Board policy and procedures
- From the relevant research ethics committee, if in the context of a clinical trial.

The ROFG secretariat should be advised of the intension to use unlicensed medicines or intravenous fluids. The ROFG secretariat will advise as to whether the use of unlicensed medicines or intravenous fluids will need ROFG approval for use or if awareness of their use is sufficient. The ROFG secretariat can be contacted via ODTresearch@nhsbt.nhs.uk

5. Activities to be Performed Under the Guidance of a Registered Medical Practitioner in Deceased and Living Donation and Transplantation

Section Contents - Hyperlinked

Section Purpose

The purpose of this section is to outline the medical procurement and transplantation activities that must be performed under the advice and guidance of a RMP, and the responsibilities of non-medical personnel who undertake medical activities.
Text in this section which is underlined is a mandatory requirement under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

5.1. Introduction

5.1.1. Specific activities in the organ procurement and transplantation process are designated **medical activities. Medical activities** must be performed under the advice and guidance of a registered medical practitioner (RMP). In practice, some **medical activities** are performed by non-medical personnel. The RMP may or may not be present.

5.1.2. Working with or without direct supervision, non-medical personnel must:

- only undertake **medical activities** in accordance with national and local organisational policies and procedures.
- adhere to their professional codes of conduct.
- only undertake **medical activities** in line with the roles and responsibilities defined in their job description and agreed with their line manager.
- be suitably qualified or trained, and competent to perform the medical activity.
- make limitations to their competence, and any training needs, known to their line manager.
- seek advice and guidance immediately from a registered medical practitioner in the event of a problem, or other extraordinary circumstances.
- Report any serious adverse event or reaction in accordance with the requirements detailed in **Guidance for licence holders: Reporting serious adverse events and reactions in relation to organs intended for transplantation**, and their employing authority incident reporting mechanism.

5.1.3. The person responsible for performing a specific **medical activity** must be identified and agreed before the activity begins.

5.1.4. Further guidance on procurement and transplantation activities is provided throughout the sections of this manual.

5.2. Medical activities to be performed under the advice and guidance of a registered medical practitioner - deceased donation

Medical Activity	Scope of the Activity performed by Non-medical Personnel	Advice and Guidance to be sought from
Review and interpretation of donor and organ characterisation information and data	The SN-OD collates information and data at the donor hospital to assist donor characterisation	Implanting and/or retrieving surgeon and NHSBT SN-OD Lead Nurse/Regional Head of Nursing/ Medical Director ODT
	The RCPoC receives information and data from the SN-OD, and from NHSBT Hub Operations, and relays information and data to the implanting surgeon	Implanting surgeon and/or retrieving surgeon
Inspection and assessment of the organ at the time of retrieval	**Performed by RMP**	Not applicable
Surgical retrieval of an organ	**Performed by RMP**	Not applicable
Flushing an organ with preservation solution	The Scrub Practitioner, or Organ Preservation Practitioner will flush the organ(s) during the retrieval process	Retrieving surgeon
Packing the organ for transport	The Scrub Practitioner, Organ Preservation Practitioner and Retrieving surgeon will package the organ(s) for transport to the recipient centre	Retrieving surgeon
Surgical implantation of an organ	**Performed by RMP**	Not applicable

5.3. Medical activities to be performed under the advice and guidance of a registered medical practitioner - living donation

Medical Activity	Scope of the Activity performed by Non-medical Personnel	Advice and Guidance to be sought from
Review and interpretation of donor and organ characterisation information and data	The LDC collates information and data to assist donor characterisation	Allocated RMPs for the donor and the recipient
	Where organs travel from a donating centre to a recipient centre (e.g. in UKLKSS, or from an adult to a paediatric facility), the LDC/RCPoC in each centre will exchange information and data, and relay it to the retrieving and implanting surgeons.	Implanting and/or Retrieving surgeon
Inspection and assessment of the organ at the time of retrieval	**Performed by RMP**	Not applicable
Surgical retrieval of an organ	**Performed by RMP**	Not applicable
Flushing an organ with preservation solution	The LDC, Scrub Practitioner or Organ Preservation Practitioner may flush the organ(s) during the retrieval process	Retrieving surgeon
Packing the organ for transport	The LDC, Scrub Practitioner or Organ Preservation Practitioner may package the organ(s) for transport to the recipient centre	Retrieving surgeon
Surgical implantation of an organ	**Performed by RMP**	Not applicable

6. Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

Section Contents - Hyperlinked

Section Purpose

The purpose of the procedure is to give guidance on the following in regard to deceased and living donation and transplantation:

- The transfer of donor and organ characterisation information
- The storage of donor and organ characterisation information
- The storage of traceability data

Text in this section which is underlined is a mandatory requirement under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

6.1. Introduction

6.1.1. To ensure the quality and safety of organs for transplantation from deceased and living donors, information must be available to ensure traceability and to permit characterisation of organ donors and donated organs.

6.1.2. Information on donor and organ characterisation must be received by the implanting surgeon within a time period that will not compromise the quality and safety of the organ.

6.1.3. The transmission of donor and organ characterisation information must ensure that the security and confidentiality of personal data is maintained.

6.1.4. Data to ensure the quality and safety of organs must be kept for 30 years after donation. This will include:

- Donor and organ characterisation information (to include records of any risk-benefit analyses undertaken if a donated organ is used in the absence of complete data, as defined in the minimum data set)
- The traceability data from HTA A and B forms
- Information on the disposal of an organ, if it is not used for transplantation
- Records of the transportation of organs arriving at, and leaving, an establishment, including the consignment record documentation, if available
- Records associated with a Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)
- Records of perfusion fluid coming into contact with an organ. At a minimum, this will include the product name and batch number.

6.2. Transfer and storage of traceability and organ and donor characterisation data

DECEASED DONATION – TRACEABILITY DATA

6.2.1. The retrieval surgeon is responsible for ensuring the completion of the relevant organ specific Donor Information form(s) and signing the completed form (**FRM4194/4147/4121/4122**). [N.B. These forms are referred to as the HTA A forms in The Quality and Safety of Organs Intended for Transplantation: A documentary framework., HTA]

6.2.2. A copy of the organ specific Donor Information form(s) (**FRM4194/4147/4121/4122**) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

DECEASED DONATION – DONOR AND ORGAN CHARACTERISATION DATA

6.2.3. NHSBT is responsible for the storage, for 30 years, of the following organ and donor characterisation data:

- Confirmation of donor identity and confirmation consent/authorisation (see Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation and Transplantation)
- Minimum mandatory data set (see Appendix 1)
- Medical and Social History (MaSH) Form **FRM4211**.
- Complementary data set **(**see Appendix 1) This must be stored for 30 years when it is considered necessary to permit adequate characterisation of a particular donor or donated organ.

LIVING DONATION – TRACEABILITY DATA

6.2.4. The retrieval surgeon is responsible for ensuring the completion of the Kidney Living Donor Assessment Pre and Post-Operative Form or the Living Liver Donor Pre and Post-Operative Assessment Form (**FRM4190, FRM4150**). [These forms are referred to as the HTA A forms in The Quality and Safety of Organs Intended for Transplantation: A documentary framework., HTA]

6.2.5. A copy of page 1 of the HTA A form (**FRM4190, FRM4150**) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

LIVING DONATION – DONOR AND ORGAN CHARACTERISATION DATA

6.2.6. The donation and/or transplant unit are responsible for the storage, for 30 years, of the following data which must be recorded in the donor and/or recipient's medical records, ensuring that confidentiality and data security measures are in place:

- Confirmation of donor identity and confirmation consent/authorisation (see Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation and Transplantation)
- Minimum mandatory data set (see Appendix 1)
- Complementary data set (see Appendix 1) This must be stored for 30 years when it is considered necessary to permit adequate characterisation of a particular donor or donated organ

6.3. Transfer and storage of perfusion fluid data

DECEASED DONATION

6.3.1. The retrieval surgeon is responsible for ensuring that the name of the perfusion solution and batch number(s) is recorded on the relevant organ specific Donor Information form(s) (**FRM4194,**

FRM4147, FRM4121, FRM4122). [N.B. These forms are referred to as the HTA A forms in The Quality and Safety of Organs Intended for Transplantation: A documentary framework, HTA].

6.3.2. A copy of the organ specific form(s) (**FRM4194, FRM4147, FRM4121, FRM4122**) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

6.3.3. In cases where an implanting surgeon inspects an organ prior to transplantation and as part of the inspection the organ is re-perfused, the name and batch number of the perfusion fluid must be recorded.

6.3.4. In circumstances where the organ is subsequently transplanted at that transplant unit, the name of the perfusion fluid and batch number recorded electronically on the HTA B Form within 3 days of transplantation. HTA B forms are available electronically with an active HTA Online account, using the PatientPath application at https://nhsbtpatientpath.crm4.dynamics.com/apps/odthub. In the rare event that access to PatientPath is unavailable, preventing electronic completion of the HTA B form, support can be obtained by emailing nhsbt.odthtaforms@nhs.net.

6.3.5. In circumstances where the organ is re-packaged for transportation to another transplant unit for transplantation, a record of the name of the perfusion solution and batch number must be noted on the organ specific form which accompanies the organ in the transport box. A copy of this form with the extra information must be returned to NHSBT by the receiving transplant centre within 7 days.

6.3.6. In cases where a liver is split for transplantation into two recipients the name and batch number of the perfusion fluid used must be recorded. If part of the liver is retained for transplantation at the 'splitting centre' the name and batch number of the perfusion fluid must be recorded electronically on the HTA B Form using an active HTA Online account to access the PatientPath application at https://nhsbtpatientpath.crm4.dynamics.com/apps/odthub.

6.3.7. In circumstances where a record of the name and batch number(s) of perfusion fluids used are recorded electronically on the HTA B Form and returned to NHSBT, the data will be stored for 30 years by NHSBT. Perfusion fluid data not recorded on an HTA B Form and returned to NHSBT must be recorded by the transplant unit to enable traceability to a transplant recipient and stored for 30 years.

LIVING DONATION

6.3.8. The retrieval surgeon is responsible for ensuring that the name of the perfusion fluid and batch number(s) is recorded on the Kidney Living Donor Assessment Pre and Post-Operative Form or the Living Liver Donor Pre and Post-Operative Assessment Form (**FRM4190, FRM4150**).

6.3.9. A copy of page 1 of the Kidney Living Donor Assessment Pre and Post-Operative Form or the Living Liver Donor Pre and Post-Operative Assessment Form (**FRM4190 FRM4150**) must be returned to NHSBT within 7 days. Once returned NHSBT are responsible for the storage of the data for 30 years.

6.4. Storage of organ transportation records

DECEASED DONATION

6.4.1. Transplant units must ensure that a record of the transportation of organs (to include date and time) being released for transportation or received for transplantation are stored for 30 years after

donation - see Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data

6.4.2. The SN-OD at the donating hospital will complete an NHSBT Organ Handover Form to ensure that transport release data (date and time) is recorded. The receiving transplant unit(s) will be required to record transport data (date and time) on receipt of the organ.

LIVING DONATION

6.4.3. Transplant units must ensure that a record of the transportation of organs (to include date and time) being released for transportation or received for transplantation are stored for 30 years after donation.

6.4.4. On delivery of the organ(s) the transplant centre must ensure that procedures are in place to record the delivery details (date and time) and for the form to be retained and stored in the transplant unit for 30 years. Transplant centres may also wish to keep local records at the retrieval/transplant centre as an alternative to using the NHSBT form.

6.5. Retrieved organ traceability

6.5.1. Transplant units must ensure that data required to ensure the traceability of organs received by their transplant unit is recorded and stored for 30 years.

6.5.2. Transplant units must ensure that on receipt of an organ, an electronic HTA B Form is completed using an active HTA Online account to access the PatientPath application at https://nhsbtpatientpath.crm4.dynamics.com/apps/odthub, and returned to NHSBT within 3 days of transplantation, who will store the data for 30 years. This form must be completed if the received organ is transplanted, the organ is used for research or the organ is disposed of in accordance with hospital policy.

7. Definitions A-Z and Associated Documents

Definitions (A-Z)

- **CE marking -** Mark given to a medical device to show that the device meets the relevant regulatory requirements, performs as intended, complies with the necessary requirement covering safety and performance and is acceptably safe. CE marking will not be recognised in Great Britain from 1 July 2023. CE marking will be recognised in Northern Ireland and medical devices placed on the Northern Ireland market must be CE marked or CE and UKNI marked.
- **Complementary Data Set -** Information required for the characterisation of organs and donors. To be collected in addition to the **minimum data set**, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.
- **Deceased donation** - Organ donation from a deceased donor.
- **Disposal -** Final placement of an organ if it is not used for transplantation or research.
- **Donor characterisation -** Collection of relevant information on the characteristics of the donor needed to evaluate his/her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient and optimise organ allocation.
- **Donor Path Application –** Electronic application used by SN-ODs to capture donor data
- **HTA -** Human Tissue Authority.
- **Implanting surgeon -** Surgeon who makes the final decision to use an organ for transplantation, also responsible for performing the transplant operation.
- **Lead Nurse / Regional Head of Nursing –** Senior nursing personnel within regional organ donation teams
- **Living donation** - Organ donation from a living donor.
- **Living Donor Co-ordinator (LDC) –** Specialist Nurse with the relevant knowledge, skills and training in living donation and transplantation.
- **Medical Activities** - Procurement or transplantation activities as defined in section 2 of this document.
- **Medical device (as defined by the MHRA) -** Healthcare products, other than medicines, used for the diagnosis, prevention, monitoring or treatment of illness or disability.
- **MHRA -** Medicines and Healthcare Products Regulatory Agency www.mhra.gov.uk
- **Minimum Data Set –** Information for the characterisation of organ and donors, which must be collected for each donation.
- **NHSBT -** NHS Blood and Transplant.
- **NHSBT Living Donor Scheme Co-ordinator -** Person working within the Data Executive at NHSBT who administers the NLDKSS.
- **Non-medical personnel** - Member of the healthcare team who is not a registered medical practitioner. This may include, but not be limited to, the Living Donor Coordinator (LDC), the Recipient Centre Point of Contact (RPoC), the Specialist Nurse - Organ Donation (SN-OD), the Scrub Practitioner.
- **NOPs –** National Operating Procedures

- **NORS Standard -** The national standards adhered to by the National Organ Retrieval Service (NORS) in relation to deceased donors (MPD1043).
- **Organ -** Differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation. For the purposes of this procedure, an organ is intended for transplantation, and includes those tissues and cells retrieved to directly support organ transplantation e.g. accessory vessels, spleen, lymph nodes.
- **Organ characterisation -** Collection of the relevant information on the characteristics of the organ needed to evaluate its suitability for transplantation, to undertake a proper risk assessment and minimise the risks for the recipient and optimise organ allocation.
- **Organ Donation Services Team (ODST) -** Organ Donation Services Team working within the Organ Donation and Transplantation Directorate. The Directorate is one of the three arms of NHS Blood and Transplant (NHSBT) providing support to transplantation services across the UK.
- **Organ Preservation Practitioner (OPP) -** Healthcare professional who facilitates the perfusion and preservation of organs as per local National Organ Retrieval Services team practice.
- **Perfusion and preservation fluid -** Fluid that is used to preserve the organ.
- **Procurement -** Process by which a donated organ becomes available for transplantation.
- **Recipient Centre Point of Contact (RCPoC) -** Healthcare professional responsible for relaying information to the implanting surgeon for a final decision to be made on accepting an organ for transplant.
- **Registered Medical Practitioner (RMP) -** Medical practitioner who is registered and with a licence to practice by the General Medical Council.
- **Retrieval -** Activity of removing an organ from a donor.
- **Retrieving surgeon -** Lead retrieval surgeon.
- **SaBTO -** Advisory Committee on the Safety of Blood, Tissues and Organs: https://www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation#history and https://www.gov.uk/government/collections/sabto-reports-and-guidance-documents
- **Scrub Practitioner -** Healthcare professional who assists the surgical team and facilitates the organ retrieval.
- **Serious Adverse Event (SAE) -** Undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.
- **Specialist Nurse - Organ Donation (SN-OD) -** Specialist Nurse with the relevant knowledge, skills and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST.)
- **Traceability -** Ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to:

- Identify the donor
- Identify the recipient and the recipient centre where the organ is implanted
- Identify the retrieving and implanting surgeons
- Locate and identify records of the perfusion solution which encounters the organ, the record must include the name of the perfusion solution and the batch number. **N.B** The details relating to the manufacturer of the perfusion fluid can be traced, if required, via the name and batch number.

- **Transplant medical team -** Members of the transplant team who are medical practitioners, licensed to practice by the General Medical Council, one of whom will be the implanting surgeon
- **Transplantation** – Process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient.
- **TransplantPath –** Digital application, containing the Core Donor Data Form (CDDF) and Medical and Social History (MaSH) form for access by the RCPoC.
- **UK Living Kidney Sharing Scheme (UKLKSS)** - Includes paired/pooled donation and altruistic donor chains initiated by non-directed altruistic donors.
- **UKCA marking –** Mark given to a medical device to show that the device meets the relevant regulatory requirements, performs as intended, complies with the necessary requirement covering safety and performance and is acceptably safe. The UKCA marking applies to most goods previously subject to CE marking. The UKCA marking came into effect on 1 January 2021.

Associated Documents (A-Z)

- **Cardiothoracic Perfusion Protocol, NORS Standards**: https://www.odt.nhs.uk/retrieval/policies-and-nors-reports/
- **Devices in Practice (2014), MHRA:** https://www.gov.uk/government/publications/devices-in-practice-checklists-for-using-medical-devices
- **FRM1538** - Authorisation - Solid Organ and Tissue Donation (Scotland)
- **FRM4121** - Kidney Donor Information (KP4)
- **FRM4122** - Deceased Donor Pancreas Information
- **FRM4122** - Deceased Donor Pancreas Information (P-DEC-DI-INTERIM)
- **FRM4147** - Liver Donor Information (L4)
- **FRM4150** - Living Liver Donor Pre and Post-Operative Assessment Form (L-LIV-DI)
- **FRM4190** - Kidney Living Donor Assessment Pre- and Post-Operative Form (L-LIV-DI)
- **FRM4194** - Cardiothoracic Donor Information (C-DI)
- **FRM4211** - Medical and Social History Questionnaire
- **FRM4281** - Consent - for Organ and/or Tissue Donation (England, Northern Ireland and Wales)
- **FRM4318** - Organ Box Address Sticker
- **FRM6199 -** NHSBT Vessels Form
- **Guidance for licence holders: Reporting serious adverse events and reactions in relation to organs intended for transplantation**, 2021, Human Tissue Authority: www.hta.gov.uk

- **MPD1043** - National Standards for Organ Retrieval from Deceased Donors
- **MPD889 -** Abdominal Perfusion and Preservation
- **MPD1043 National Standards for Organ Retrieval Standards from Deceased Donors:** https://www.odt.nhs.uk/retrieval/policies-and-nors-reports/
- **NHSBT Patient Selection and Allocation Policies:** www.odt.nhs.uk
- **POL188 -** Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation
- **The British Transplantation Society Guidelines for Living Donor Kidney Transplantation (March 2018):** https://bts.org.uk/guidelines-standards/
- **The Medical Devices Regulations 2002 (Statutory Instrument 2002/618)** http://www.legislation.gov.uk/uksi/2002/618/pdfs/uksi_20020618_en.pdf
- **The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations (2012):** https://www.legislation.gov.uk/uksi/2012/1501/contents
- **The Quality and Safety of Organs Intended for Transplantation: A Documentary Framework (2022):** https://www.hta.gov.uk/guidance-professionals/guidance-sector/organ-donation-and-transplantation/quality-and-safety-organs

8. Appendix

Appendix 1

Part A

Minimum Data Set

This information **must** be collected for **all** donors: *if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all the minimum data specified in Part A of the Annex are available. This is solely the decision of the Consultant Transplant Surgeon.*

- The establishment where the procurement takes place and other general data
- Type of donor
- Blood group
- Gender
- Cause of death (in deceased donation)
- Date of death (in deceased donation)
- Date of birth or estimated age
- Weight
- Height
- Past or present history of IV drug abuse
- Past or present history of malignant neoplasia
- Present history of other transmissible disease
- HIV; HCV; HBV tests
- Basic information to evaluate the function of the specific donated organ, defined by the Chairpersons of the UK Solid Organ Advisory Groups.

Part B

Complementary Data Set

This information **must** be collected **when it is considered necessary** to assess the suitability of a **particular** donor and donor organ:

GENERAL DATA

- Contact details of the procurement organisation/the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

DONOR DATA

- Demographic and anthropometrical data required to guarantee an appropriate matching between the donor/organ and the recipient.

DONOR MEDICAL HISTORY

- Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

PHYSICAL AND CLINICAL DATA

- Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.

LABORATORY PARAMETERS

- Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

IMAGE TESTS

- Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

THERAPY

- Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.