

This National Operating Procedure replaces: NOP003

Effective: 6th December 2016

Summary of Significant Changes

Document updated to reflect changes in organ packaging and labelling including minor changes to terminology.

Policy

In order to maintain the quality and integrity of an organ for transplantation, safeguard potential transplant recipients, to ensure traceability, and to minimise any potential risk, it is vital that organs and their accompanying blood and tissue samples are packaged, labelled and transported to the recipient centre appropriately and in a timely manner.

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. It will include the 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 document which is underlined is a mandatory requirement under the Quality and Safety of Organs for Transplantation Regulations 2012 (Updated July 2014).

Responsibilities

Healthcare professionals who undertake activities related to the packaging, labelling and transport of organs for transplantation are responsible for working according to this procedure. This will include the

- **Living Donor Coordinator (LDC)**
- **Organ Preservation Practitioner**
- **Recipient Centre Point of Contact (RPoC)**
- **Retrieving surgeon**
- **Scrub Practitioner**

Definitions

Donor characterisation - Collection of the relevant information on the characteristics of the donor needed to evaluate their suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation. For further information on the definition of relevant information see ***NOP001v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation***

EU Directive/European Union Directive - Directive 2010/53/EU of the European Parliament and of the Council 7 July 2010 (amended 2014) on standards of quality and safety of human organs intended for transplantation.

Living Donor Coordinator (LDC) - Specialist Nurse with the relevant knowledge, skills and training in living donation and transplantation.

UK Living Kidney Sharing Scheme (UKLKSS) - Includes paired/pooled donation, altruistic donation and altruistic donor chains.

NHSBT – NHS Blood and Transplant

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 considered to be 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, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation. For further information on the definition of relevant information see ***NOP001v2 Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation***

Organ Preservation Practitioner - Healthcare professional who facilitates the perfusion and preservation of organs as per local National Organ Retrieval Services team practice.

Recipient Centre Point of Contact (RPOC) - Healthcare professional responsible for communicating 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.

Retrieving surgeon - The lead retrieval surgeon.

Scrub Practitioner – Healthcare professional who assists the surgeons and facilitates the organ retrieval.

Applicable Documents

Directive 2010/53/EU of the European Parliament and of the Council 7 July 2010 (amended 2014) on standards of quality and safety of human organs intended for transplantation

FRM4121 - Kidney Donor Information (KP4)

FRM4122 - Deceased Donor Pancreas Information (P-DEC-DI-INTERIM)

FRM4147 - Liver Donor Information (L4)

FRM4194 - Cardiothoracic Donor Information (C-DI)

FRM4318 - OOrgan Box Address Sticker

MPD1043 - National Standards for Organ Retrieval from Deceased Donors

NOP001 - Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation

NOP005 - Activities to be Performed under the Guidance of a Registered Medical Practitioner in Deceased and Living Donation and Transplantation

NOP006 - Transfer And Storage Of Donor And Organ Characterisation Information and Storage Of Traceability Data

The Quality and Safety of Human Organs Intended for Transplantation - a documentary framework, 2012, (updated July 2014) Human Tissue Authority, www.hta.gov.uk

Packaging, Labelling and Transport of Organs in Deceased and Living Donation and Transplantation

1. INTRODUCTION

- 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.
- 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.

2. PACKAGING AN ORGAN FOR TRANSPORT

- 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 is provided in ***NOP005v2 Activities To Be Performed Under The Guidance Of A Medical Practitioner in Deceased and Living Donation***.
- 2.2. Any practitioner undertaking responsibility for preparing and packaging an organ for transport must be appropriately trained and experienced in the role. The RMP must be present in theatre, and advice must be sought immediately in the event of a problem being identified.
- 2.3. Organs must be prepared for packaging in THREE bags in line with European Practice. All organs should be prepared for packaging as follows
 - Each organ is submerged in sufficient cold preservation solution in the first bag
 - The second bag is filled with a least 250 cold saline (without any ice)
 - A small amount of fluid (sufficient to ensure there is no air in the bag) shall be placed between the second and third bags
 - Important: each bag is firmly tied after adequate de-airing
- 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.
- 2.5. The person responsible for packing the organ in the transport box for transport should check the organ transport box to 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.

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2.6. For NHSBT organ transport boxes cable ties must be used to seal both sides of the transport box

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 e.g. right kidney, left kidney, liver lobe.
- That the organ has been surrounded by perfusion/preservation fluid and bagged according to the agreed procedure.

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

2.9. The following actions should be taken for all organs

- The organ must be contained and covered by melting water 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
- Before transportation, and where applicable, the box must be sealed on both sides with tie wrap straps/cable ties (where possible) and a note made of the ID number of the box.

3. LABELLING AND PACKAGING OF TISSUE/BLOOD SAMPLES TO ACCOMPANY AN ORGAN IN DECEASED DONATION

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
- Hospital ID number/CHI number (Scotland)

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. Blood vessels, if required, must be placed into appropriately labelled sterile 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.

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4. IDENTIFICATION AND LABELLING OF AN ORGAN TRANSPORT BOX

4.1. The organ transport box must be clearly labelled to show that an organ is being transported. The following must be visible on the box

- “Handle With Care”
- “Organ in Transit”
- After deceased donation, the contact telephone number for NHSBT Duty Office (+441179757575).
- 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 address
- Specific instructions on the required transport conditions e.g. keep upright.

4.2. The transport box must be labelled using either a plasticised luggage label or the Organ Box Sticker (FRM 4138)

5. DOCUMENTATION TO ACCOMPANY AN ORGAN

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

5.2. Information on donor characterisation (deceased donor), will be available electronically via the Electronic Offering System (EOS). Information that cannot be entered electronically will have been communicated via the RPoC or the NHSBT Duty Office, by secure fax, or directly to the implanting surgeon.

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.

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.

6. SEALING THE ORGAN TRANSPORT BOX

6.1. The organ transport box must be secured. Where applicable, cable ties should be used to ensure that the box remains closed on both sides (where possible). Box ID/tag/asset numbers for each organ must be relayed to NHSBT Duty Office to maintain traceability from the donating hospital to the recipient centre

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7. ARRANGING TRANSPORT OF AN ORGAN

7.1. The transport of organs must only be arranged through locally agreed transport provider organisations.

7.2. There should 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.

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 routing/GPS tracking facilities
- Ensure the relevant licences for all vehicles and drivers

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

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

8. RELEASING AN ORGAN FOR TRANSPORT

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

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.

8.3. For traceability, records of organs released for transport must be stored for 30 years (see ***NOP006v2 Transfer And Storage Of Donor And Organ Characterisation Information and Storage Of Traceability Data***).

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9. RECEIPT OF THE DONOR ORGAN AT THE RECIPIENT CENTRE

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.

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 the NHSBT Duty Office/RPoC/donating hospital LDC.
- Check that the Organ box ID number (if attached) correlates with that given by the NHSBT Duty Office/RPoC/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.

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.

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.

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.

9.6. Check the box inside and out for any damage, particularly any damage to the seal inside the lid. If any damage is noted, inform odtcommissioning@nhsbt.nhs.uk

9.7. For traceability, records of organs arriving at a recipient centre must be stored for 30 years (See **NOP006v2 Transfer And Storage Of Donor And Organ Characterisation Information and Storage Of Traceability Data**).

10. IMPLEMENTATION AND AUDIT

10.1. The National Operating Procedures (NOPs) are available to download from the NHSBT ODT Clinical website at www.odt.nhs.uk

10.2. Transplant Units may

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

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

10.4. Accountability for the NOPs and their implementation will lie with each individual Transplant Unit.

10.5. Transplant Units will be responsible for

- Implementation of the NOPs 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

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