POL281/1.3 – National Operating Procedure NOP004 Management of Procurement Material and Equipment in Deceased and Living Donation and Transplantation

Changes in this version

No major changes, update to owner and review date box.

Policy

Procurement materials and equipment which could affect the quality and safety of an organ must be managed in accordance with The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended), relevant international and national legislation, standards and guidelines on the sterilisation of devices.

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

Responsibilities

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 Donor Coordinator (LDC)**
- **Organ Preservation Practitioner (OPP)**
- **Retrieving surgeon**
- **Scrub Practitioner**
- **Specialist Nurse - Organ Donation (SN-OD)**

1. Introduction

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.

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

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.

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.

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

2. Medical devices

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

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

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

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, Innovation, Novel Technologies Advisory Group (RINTAG) secretariat should be advised of new medical devices under development. The RINTAG secretariat will advise as to whether the medical device will need RINTAG approval for use or if awareness of use of the medical device is sufficient. The RINTAG secretariat can be contacted via ODTresearch@nhsbt.nhs.uk

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).

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

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).

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

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.

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)

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

3. Reusable medical devices

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.

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

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

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. Perioperative management of procurement materials and equipment

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.

4.2. 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.

4.3. 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. 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 POL280 (NOP003) Packaging, Labelling and Transport of Organs in Deceased and Living Donation and Transplantation***).

- 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.

5. Perfusion fluids

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 provided in ***POL282 (NOP005) Activities to Be Performed under the Guidance of a Registered Medical Practitioner in Deceased and Living Donation and Transplantation.***

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.

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

5.4. In deceased and living donation, details of perfusion fluids used to perfuse each organ must be recorded on the relevant HTA 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:

- Manufacturer
- Batch number
- Time and volume of fluid perfused

5.5. 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 ***POL283 (NOP006) Transfer and Storage Of Donor and Organ Characterisation Information and Storage Of Traceability Data).&***

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

6. Medicines and intravenous fluids

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

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

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

7. Implementation and audit

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

7.2. Transplant Units may

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

7.3. If the NOPs are 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 2012 (as amended) and in accordance with the regulatory framework of the HTA: The Quality and Safety of Human Organs Intended for Transplantation - a documentary framework.

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

7.5. 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

Next Review Date	**April 2025**
Document Owner	**Laura Stamp**

Definitions

- **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.
- **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.
- **Implanting surgeon -** Surgeon who makes the final decision to use an organ for transplantation, also responsible for performing the transplant operation.
- **Living Donor Coordinator (LDC) -** Specialist Nurse with the relevant knowledge, skills and training in living donation and transplantation
- **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
- **NHSBT –** National Health Service Blood and Transplant
- **NOPs –** National Operating Procedures
- **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 Preservation Practitioner -** 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.
- **Registered Medical Practitioner (RMP) -** means a 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.
- **Scrub Practitioner -** Healthcare professional who assists the surgical team and facilitates the organ retrieval.

- **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.)

Applicable Documents

- The Medical Devices Regulations 2002 (Statutory Instrument 2002/618) http://www.legislation.gov.uk/uksi/2002/618/pdfs/uksi_20020618_en.pdf
- Devices in Practice (2014), MHRA https://www.gov.uk/government/publications/devices-in-practice-checklists-for-using-medical-devices
- **POL280 (NOP003)** Packaging, Labelling and Transport of Organs in Deceased and Living Donation and Transplantation
- **POL282 (NOP005)** Activities to Be Performed Under The Guidance Of A Registered Medical Practitioner in Deceased and Living Donation and Transplantation
- **POL283 (NOP006)** Transfer and Storage Of Donor And Organ Characterisation Information and Storage Of Traceability Data
- The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended), (Statutory Instrument 2012/1501) http://www.legislation.gov.uk/uksi/2012/1501/data.pdf The Quality and Safety of Organs Intended for Transplantation: A documentary framework. Human Tissue Authority, www.hta.gov.uk
- Using the UKCA marking, GOV.UK www.gov.uk/guidance/using-the-ukca-marking