

Changes in this version

New

Policy

To ensure quality and safety, the European Union Directive 2010/53/EU stipulates that the healthcare personnel involved at all stages of the chain from donation to transplantation, or disposal, are suitably qualified or trained, and competent.

Specific **medical activities** in the organ donation and transplantation process must be performed under the advice and guidance of a Registered Medical Practitioner (RMP).

The responsibility for the defined **medical activities** lies with the RMP.

Purpose

The purpose of this document 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 document which is underlined is a mandatory requirement under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

Responsibilities

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

1. Introduction

- 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.

- 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.

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

- 1.4. Further guidance on procurement and transplantation activities is provided in the National Operating Procedures as listed on page 6 of this document.

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 |
|---|--|--|
| <u>Review and interpretation of donor and organ characterisation information and data</u> | The SN-OD collates information and data at the donor hospital to assist donor characterisation | Implanting surgeon and/or retrieving surgeon and NHSBT SNOD Team Manager/Regional Manager/Associate 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 |
| <u>Inspection and assessment of the organ at the time of retrieval</u> | Performed by RMP | Not applicable |
| <u>Surgical retrieval of an organ</u> | Performed by RMP | Not applicable |
| <u>Flushing an organ with preservation solution</u> | The Scrub Practitioner, or Organ Preservation Practitioner will flush the organ(s) during the retrieval process | Retrieving surgeon |
| <u>Packing the organ for transport</u> | The Scrub Practitioner, Organ Preservation Practitioner and Retrieving surgeon will package the organ(s) for transport to the recipient centre | Retrieving surgeon |
| <u>Surgical implantation of an organ</u> | Performed by RMP | Not applicable |

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 |
|---|--|--|
| <u>Review and interpretation of donor and organ characterisation information and data</u> | 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 |
| <u>Inspection and assessment of the organ at the time of retrieval</u> | Performed by RMP | Not applicable |
| <u>Surgical retrieval of an organ</u> | Performed by RMP | Not applicable |
| <u>Flushing an organ with preservation solution</u> | The LDC, Scrub Practitioner or Organ Preservation Practitioner may flush the organ(s) during the retrieval process | Retrieving surgeon |
| <u>Packing the organ for transport</u> | The LDC, Scrub Practitioner or Organ Preservation Practitioner may package the organ(s) for transport to the recipient centre | Retrieving surgeon |
| <u>Surgical implantation of an organ</u> | Performed by RMP | Not applicable |

4. Implementation and Audit

- 4.1. The National Operating Procedures (NOPs) are available to download from the NHSBT ODT Clinical website at www.odt.nhs.uk
- 4.2. Transplant Units may
- Adopt the NOPs fully
 - Adopt the NOPs with local adaptation
 - Write their own procedural documents
- 4.3. 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 and in accordance with the regulatory framework of the HTA: *The Quality and Safety of Human Organs Intended for Transplantation - a documentary framework*.
- 4.4. Accountability for the NOPs and their implementation will lie with each individual Transplant Unit.
- 4.5. 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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POL282/1 – National Operating Procedure NOP005 Activities to be Performed Under the Guidance of a Registered Medical Practitioner in Deceased and Living Donation and Transplantation



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Definitions

- **Deceased donation** - Organ donation from a deceased donor.
- **EU Directive/European Union Directive** - Directive 2010/53/EU of the European Parliament and of the Council 7 July 2010 on standards of quality and safety of human organs intended for transplantation.
- **Implanting Surgeon** - Surgeon who makes the final decision to use an organ for transplantation, also responsible for performing the transplant operation.
- **Living donation** - Organ donation from a living donor.
- **Living Donor Coordinator (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.
- **NHSBT** – National Health Service Blood and Transplant.
- **NOPs** – National Operating Procedures.
- **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.
- **Organ Preservation Practitioner** - Healthcare professional who facilitates the perfusion and preservation of organs as per local National Organ Retrieval Services (NORs) team practice.
- **Recipient Centre Point of Contact (RCPoC)** - 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** - Lead retrieval surgeon.
- **Scrub Practitioner** - Healthcare professional who assists the surgeons 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).
- **UK Living Kidney Sharing Scheme (UKLKSS)** - Includes paired/pooled donation, altruistic donation and altruistic donor.

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Applicable Documents

- Directive 2010/53/EU of the European Parliament and of the Council 7 July 2010 on standards of quality and safety of human organs intended for transplantation.
- **POL278 (NOP001)** - Donor and Organ Characterisation, Assessment and Allocation in Deceased and Living Donation and Transplantation
- **POL279 (NOP002)** - Verification of Donor Identity, Consent/Authorisation and Organ and Donor Characterisation in Deceased and Living Donation and Transplantation
- **POL280 (NOP003)** - Packaging, Labelling and Transport of Organs for Transplantation in Deceased and Living Donation and Transplantation
- **POL281 (NOP004)** - Management of Procurement Material and Equipment in Deceased and Living Donation and Transplantation
- **POL283 (NOP006)** - Transfer and Storage of Donor and Organ Characterisation Information and Storage of Traceability Data
- **Guidance for licence holders: Reporting serious adverse events and reactions in relation to organs intended for transplantation**, 2015, Human Tissue Authority, www.hta.gov.uk
- The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2015, (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