Blood and Transplant Copy No: Effective date: 29/03/2023

#### Changes in this version

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

#### **Policy**

To ensure quality and safety, The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) 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 <u>underlined</u> is a mandatory requirement under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

### 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.

(Template Version 03/02/2020)

Blood and Transplant Copy No: Effective date: 29/03/2023

#### 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.

Blood and Transplant Copy No: Effective date: 29/03/2023

# 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 surgeon and/or retrieving surgeon and NHSBT SNOD Team Manager/Regional Manager/ 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

Blood and Transplant Copy No: Effective date: 29/03/2023

# 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
	The LDC collates information and data to assist donor characterisation	Allocated RMPs for the donor and the recipient
Review and interpretation of donor and organ characterisation information and data	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

Blood and Transplant Copy No: Effective date: 29/03/2023

### 4. Implementation and Audit

- 4.1. The National Operating Procedures (NOPs) are available to download from the NHSBT ODT Clinical website at <a href="https://www.odt.nhs.uk">www.odt.nhs.uk</a>
- 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

Next Review Date	April 2025
<b>Document Owner</b>	Laura Stamp

Blood and Transplant Copy No: Effective date: 29/03/2023

#### **Definitions**

- **Deceased donation** Organ donation from a deceased donor.
- **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.

(Template Version 03/02/2020)

Blood and Transplant Copy No: Effective date: 29/03/2023

#### **Applicable Documents**

- 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, <a href="www.hta.gov.uk">www.hta.gov.uk</a>
- The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2015,
   (Statutory Instrument 2012/1501) <a href="http://www.legislation.gov.uk/uksi/2012/1501/data.pdf">http://www.legislation.gov.uk/uksi/2012/1501/data.pdf</a> The Quality and Safety of Organs Intended for Transplantation: A documentary framework. Human Tissue Authority, <a href="https://www.hta.gov.uk">www.hta.gov.uk</a>