

The Quality and Safety of Organs Intended for Transplantation

Assessment criteria

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Donor characterisation and organ characterisation

- CT1)** Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.
- CT2)** Donors and organs are characterised before implantation by the collection of information specified in Annex A of The Quality and Safety of Organs Intended for Transplantation: A documentary framework.
- CT3)** Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Annex B of The Quality and Safety of Organs Intended for Transplantation: A documentary framework.
- CT4)** All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.
- CT5)** Tests required for donor and organ characterisation are carried out by laboratories with United Kingdom Accreditation Service (UKAS) accreditation (to ISO15189:2012).
- CT6)** Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.

Retrieval of organs for transplantation

- R1)** Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.
- R2)** Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
- R3)** Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.

- R4)** Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.

Organ preservation

- P1)** Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
- P2)** Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
- P3)** Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.

Making arrangements to transport an organ

- TP1)** The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.
- TP2)** The organ shipping container is suitable for transport of the specified organ.
- TP3)** The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in The Quality and Safety of Organs Intended for Transplantation: A documentary framework, and there is an operating procedure in place to demonstrate how this requirement is complied with.
- TP4)** Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.
- TP5)** Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.

Implantation

- I1)** The identification of the donor and the collection of the information in Annex A and B of The Quality and Safety of Organs Intended for Transplantation: A

documentary framework, are verified prior to proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.

- I2) Compliance with the conditions of preservation and transport outlined in The Quality and Safety of Organs Intended for Transplantation: A documentary framework are verified prior to proceeding to implant an organ.
- I3) Where any of the information specified in Annex A of The Quality and Safety of Organs Intended for Transplantation: A documentary framework is not available, a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.

Traceability – (these criteria apply to all licensed activities)

- TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
- TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
- TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.

Serious adverse events and reactions (SAEARs) – (these criteria apply to all licensed activities)

- S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.
- S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.
- S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.

General – (these criteria apply to all licensed activities)

- GN1)** Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.
- GN2)** Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.
- GN3)** Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.