

Site visit audit report
Site visit date: 22 - 24 March 2022



Newcastle upon Tyne Hospitals NHS Foundation Trust
HTA licensing number 40045

Licensed under the Human Tissue Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

Licensed activities – Procurement

Organ type	Liver	Kidney	Pancreas	Heart	Lung
Adult living	DC, OC, P, T, R	DC, OC, P, T, R	-	-	-
Adult deceased	DC, OC, P, T, R	DC, OC, P, T, R	DC, OC, P, T, R	DC, OC, P, T, R	DC, OC, P, T, R
Paediatric deceased	DC, OC, P, T, R	DC, OC, P, T, R	DC, OC, P, T, R	DC, OC, P, T, R	DC, OC, P, T, R

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)

Licensed activities – Transplant

Organ type	Liver	Kidney	Pancreas	Heart	Lung
Adult	OC, P, T, I	OC, P, T, I	OC, P, T, I	OC, P, T, I	OC, P, T, I
Paediatric	-	DC, OC, P, T, R	-	OC, P, T, I	OC, P, T, I

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)

Summary of audit findings

Newcastle upon Tyne Hospitals NHS Foundation Trust (the establishment) was found to have met all HTA assessment criteria that were assessed as part of the audit.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA assessment criteria

All applicable HTA assessment criteria have been assessed as fully met.

Advice

The HTA advises the establishment to consider the following to further improve practice:

Number	Assessment Criterion	Advice
1.	R4	<p>The establishment follows up living kidney donors immediately post-surgery, at one-week post-surgery, then one and three months post-surgery before annual follow-up at the living donor clinic. Living donors are discharged into the care of their GP in addition to their annual follow-up at the establishment or their local hospital.</p> <p>Upon discharge, a letter is sent to the donor's GP. At the point of the donor going on to the annual follow-up pathway, the establishment is advised to consider sending an additional letter to the donor's GP. This is to remind them that should the living donor present with any medical conditions which may have an impact on the organ recipient, the establishment should be contacted immediately so that the recipient can be reviewed and followed up as necessary.</p> <p>This may facilitate earlier detection of medical conditions that could impact an organ recipient. This is of particular importance in cases of non-directed altruistic living donations where there is no link between a donor and recipient.</p>

Number	Assessment Criterion	Advice
2.	S1	<p>The review of incidents at the establishment showed that incidents are identified and reported appropriately. However, an incident can be reported and followed up by different members of the establishment's transplant staff meaning others in different teams are not aware of the incident.</p> <p>The establishment is advised to create a centralised record where staff from all parts of the organ transplant pathway can record that an incident was identified, reported, investigated, followed up and closed. This may help establishment staff to have greater oversight of incidents and help ensure that all incidents have been followed up, closed and any lessons learnt shared.</p> <p>In addition, incidents may be reported on the establishment's internal incident reporting system. It is not possible to readily identify transplant-related incidents.</p> <p>The establishment is advised to consider a way of "tagging" transplant-related incidents so that these incidents may be trended, and any lessons learnt shared.</p>
3.	General	<p>The establishment maintains a stock of perfusion fluid in both a fridge and a storeroom within the theatre complex. This fluid has a maximum storage temperature of 25°C. This storeroom is not temperature monitored. The establishment is advised to continue to monitor the temperature of the storeroom so that it may assure itself that stock is being maintained at the correct temperature.</p>

Background

The establishment operates at both the Freeman Hospital and the Royal Victoria Infirmary (RVI). The Freeman Hospital is where the Institute of Transplantation (IoT) is located and where adult kidney, pancreas, liver, heart and lung recipients are treated. Paediatric heart

and lung transplantation are also carried out at the Freeman Hospital and paediatric kidney transplants take place at the RVI.

Since the last audit in 2017, the establishment has introduced an electronic system for patients' clinical and operation notes.

The COVID - 19 pandemic posed challenges to the establishment, but staff were able to maintain their national organ retrieval service (NORS) responsibilities. In addition, staff participated in Multi-Disciplinary Team meetings and transplanted patients listed for transplants at establishments in the Midlands and London and offered to undertake liver transplants on behalf of South of England sites.

The establishment has been developing its systems to facilitate the prompt return of transplant-related documentation to NHS Blood and Transplant, as required by the regulations.

Cardiothoracic

The establishment has previously undertaken retrievals from donors following circulatory death (DCD) using a portable mechanical organ perfusion system that can preserve a donor heart in a near-normothermic beating state from retrieval until transplantation. However, this is now being undertaken at specified centres and the establishment, if required, uses the perfusion system for complex cases involving hearts from deceased donors following death by neurological criteria (DBD).

The programme using ex vivo mechanical lung perfusion (EVLP) has ceased.

Abdominal

The number of consultants has increased with two consultants on-call and on some occasions, a further supporting consultant may be available for transplantation. The Freeman Hospital works with another establishment on the occasions when staff are not available to undertake retrieval activity.

Description of audit activities undertaken

The HTA's regulatory requirements are set out in Appendix 1 and 3.

As part of the audit, the following areas were covered:

Review of governance documentation

Procedural documents relating to licensed activities, accreditation certificates for the Histocompatibility and Immunogenetics (H&I), Histopathology and Microbiology laboratories, the procurement policy demonstrating how the Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002) requirement is complied with and certification of the sterile services provider.

In addition, a selection of incidents, including those from both abdominal and cardiothoracic teams, were reviewed and discussed with establishment staff.

Visual inspection

A visit was made to the operating theatres where abdominal organs are transplanted and the cardiothoracic theatres where hearts and lungs are transplanted. In both of these areas, discussions around temperature monitoring of the relevant perfusion fluids took place. The area where equipment and perfusion fluids are kept by the establishment's NORS teams was also reviewed. In addition, the team visited the RVI where paediatric kidney transplants take place to review the organ pathway from receipt to implantation.

Audit of records

The following transplant records were reviewed:

Three heart transplants, from one DBD donor and two DCD donors.

Two lung transplants from DBD donors.

Three sets of living kidney donation transplant records including one live unrelated donor transplant, a live related donor transplant, and an altruistic donor transplant.

Four cadaveric kidney transplants from three DBD donors and one DCD donor.

Two simultaneous pancreas and kidney (SPK) transplants from one DBD donor and one DCD donor.

The transplant of a pancreas, from a DBD donor, into a recipient who had already received a kidney transplant.

Two liver transplants from DBD donors.

The records reviewed included HTA - A and electronic HTA - B forms, recipient consent, records of receipt of the organs, copies of donor information from the electronic offering system (EOS), records of perfusion fluids used, and transplant coordinator notes. No anomalies were identified as part of the review.

Report sent for factual accuracy: 21 April 2022

Report returned with comments: 14 June 2022. No final factual accuracy or requests for redaction comments were made.

Final report issued: 16 June 2022

Appendix 1: The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria:

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.

Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that an assessment criterion is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an assessment criterion, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of the risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to the quality of an organ intended for transplantation or which poses a significant direct risk of causing harm to a donor or recipient.

or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

- (1) A notice of proposal being issued to revoke the licence
- (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall; a shortfall in the carrying out of licensable activities which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient;

or

A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012 (as amended)** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting quality and safety of an organ intended for transplantation or the safety of a donor or recipient;

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final audit report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk-based review or at the time of the next audit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final audit report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final audit report. The establishment must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of:

- a follow-up site-visit audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site-visit audit

After an assessment of the proposed action plan, the establishment will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA Assessment criteria

The HTA assessment criteria applicable to this establishment are shown below; those not assessed during the VRA are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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 endeavored to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information. (The establishment is not responsible for obtaining information relating to a deceased donor. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence).
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 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 ISO15189:2021).
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 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 adverse 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.