Site visit audit report
Audit date: 30 November & 1-2 December 2022

Leeds Teaching Hospitals NHS Trust

HTA licensing number 40040

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

Licensed activities – Procurement

Organ type	Kidney	Liver	Composite tissue - Limbs
Adult living	**DC, OC, P, R**	**DC, OC, P, R**	
Adult deceased	**DC, OC, P, R**	**DC, OC, P, R**	**DC, OC, P, R**
Paediatric deceased	**DC, OC, P, R**	**DC, OC, P, 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)

Licensable activities – Transplantation activities

Organ type	Kidney	Liver	Composite tissue - Limbs
Adult living	**OC, P, T, I**	**OC, P, T, I**	
Adult deceased	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**
Paediatric deceased	**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

Leeds Teaching Hospitals NHS Trust (LTHT) (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.	CT2	The establishment is advised to ask potential living donors whether they have undergone any cosmetic procedures involving penetration by needles, for example cosmetic tattoos, and to record the responses as part of the donor characterisation information.
2.	CT2	The establishment is advised to record travel plans of living organ donors in the donor records.
3.	CT4	The establishment uses mechanical perfusion devices to assess the function of donated organs and to extend, if required, the time prior to implantation. Key parameters relating to the organ function are documented. However, information relating to the performance of the mechanical device is not; this information is retained on the device. The establishment is advised to consider storing this data on the Trusts' backed-up IT system for the required 30 years.

Background

Leeds Teaching Hospitals NHS Trust (LTHT) has been licensed by the HTA since August 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended. Licensable activities are undertaken at St James's University Hospital (SJUH) and Leeds General Infirmary (LGI).

Since the last audit, the establishment has rationalised the transplant pathways. Assessments have been streamlined resulting in a reduction in the waiting time between investigations.

On arrival at the establishment, livers may be placed on a mechanical perfusion device to allow the transplant surgeon to assess the organ and if required, extend the time prior to implantation.

The establishment does not use mechanical perfusion devices when kidneys are received at the establishment. However, the renal department is currently participating in the HOPE (hypothermic oxygenated perfusion) trial to determine how pumping oxygen into a kidney from a deceased donor, can help preserve the condition of the organ prior to transplant.

LTHT continues to be the only establishment offering a hand and upper limb transplant (HAUL) programme.

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:

Criteria assessed during the audit

The establishment was assessed against 29 of the 30 applicable criteria. The criteria CT1 was not applicable as the establishment is not responsible for obtaining information relating to a deceased donor.

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 were reviewed and discussed with establishment staff.

Visual inspection

A visit was made to the ward and operating theatres where organs are received and stored prior to transplantation. The areas where perfusion fluids are stored and the temperature monitoring records of the fluid storage fridges were reviewed. In addition, the areas where the equipment and perfusion fluids are kept by the establishment's NORS teams and the room where a mechanical perfusion device is stored were visited. See advice and guidance.

Audit of records

The following transplant records were reviewed:

Two liver transplants from donors following circulatory death (DCD) where mechanical prefusion was used.

Two liver transplants from donors following death by neurological criteria (DBD) including one where mechanical prefusion was used

Two sets of living liver donation transplant records including a live related donor transplant and an altruistic donor transplant.

Three cadaveric kidney transplants from two DBD donors and one DCD donor where mechanical prefusion was used.

Three sets of living kidney donation transplant records including a live related donor transplant, two pair-pooled transplants and an altruistic donor transplant.

One set of transplant records for hand and upper limb transplant.

The records reviewed included HTA - A and 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.

Report sent for factual accuracy: 29 December 2022

Report returned with comments: 9 January 2023 No factual accuracy or request for redaction comments were made.

Final report issued: 9 January 2023

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 audit are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Donor Characterisation and Organ Characterisation

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 ISO15189:2021).
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.