

Audit report on compliance with licensing assessment criteria

Date: 4-6 December 2024



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 - limb
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)

Licensed activities – Transplant

Organ type	Kidney	Liver	Composite tissue - limb
Adult recipient	OC, P, T, I	OC, P, T, I	OC, P, T, I
Paediatric recipient	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 (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 clarify the wording used in the establishment's two living donor questionnaires. Rather than a reference to recreational drugs, the language should reflect the wording of Annex A of The Quality and Safety of Organs Intended for Transplantation: a documentary framework which refers to 'Past or present history of IV drug abuse' . This may also be expanded to include use of injectable steroids or other substances.
2.	CT5	Should the establishment's laboratory services lose, or have its accreditation suspended, in the future the establishment is advised to undertake a risk assessment to assure the suitability of continuing to use the laboratory services in these circumstances.
3.	P3	During the audit of temperatures where reagents used during retrieval are stored, a fridge was found to be at the lowest storage temperature as set by the fluid manufacturer. Although within the required range, the consistent low temperature may be indicative of a future failure of the fridge. The

Number	Assessment Criterion	Advice
		establishment may wish to consider introducing trend analysis of fridge temperatures to assure itself that the fridges continue to operate as expected.
4.	TC3	<p>The establishment may wish to consider conducting an audit of records for completeness relating to all living and deceased transplant programmes.</p> <p>The establishment may also wish to consider recording the NHSBT INC number on the kidney benching form where there has been damage identified and reported as a serious adverse event. This may help in following up of reported incidents.</p> <p>The establishment may wish to consider completing a risk assessment relating to the follow up of living donors from overseas where the establishment may no longer be in contact with.</p> <p>The establishment is advised to remind staff to correct transcription errors as per the Trust's record management policy so that the original record remains readable.</p>
5.	N/A	<p>The establishment is advised to include the following when Trust documents are next reviewed and updated.</p> <ul style="list-style-type: none"> • Refer to the latest version of The Quality and Safety of Organs Intended for Transplantation: a documentary framework which was updated in November 2022; • Include the recent reporting changes required by the new legislation in the living liver donation pathway standard operating procedure (SOP); and • Ensure that all SOPs continue to reflect current practice.

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. This was the establishment's fourth audit; the most recent previous audit took place in November 2022. Licensable activities are undertaken at St James's University Hospital (SJUH) and Leeds General Infirmary (LGI).

Since the audit in November 2022, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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 against 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 deceased donors.

Review of governance documentation

Procedural documents relating to licensed activities were reviewed and included 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) are 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:

Three liver transplants from donors following circulatory death (DCD) where mechanical perfusion was used.

Three liver transplants from donors following death by neurological criteria (DBD).

Four sets of living liver donation transplant records including three directed donor transplants and a non-directed altruistic donor transplant.

Four deceased donor kidney transplants.

Five sets of living kidney donation transplant records including three directed donor transplants, one paired/pooled transplant and a non-directed altruistic donor transplant.

One set of transplant records for a 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 TransplantPath, records of perfusion fluids used, and transplant coordinator notes.

Report sent for factual accuracy: 19 December 2024

Report returned with comments: 23.12 2024

Final report issued: 10 January 2025

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

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 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.