Site visit audit report
Audit date: 17 and 18 June 2025

Cambridge University Hospitals NHS Foundation Trust

HTA licensing number 40032

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

Licensed activities – Procurement

Organ type	Kidney	Pancreas	Liver	Small Bowel
Adult living	**DC, OC, P, T, R**		**DC, OC, P, T, R**	
Adult deceased	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**	**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)

Licensable activities – Transplantation activities

Organ type	Kidney	Pancreas	Liver	Small Bowel
Adult living	**OC, P, T, I**		**OC, P, T, I**	
Adult deceased	**OC, P, T, I**	**OC, P, T, I**	**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
Cambridge University 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.

Background

Cambridge University Hospitals NHS Foundation Trust (CUH) has been licensed by the HTA since July 2012. Licensable activities are undertaken at the Addenbrooke's Hospital site.

Since the last audit, two legislative changes have been made. The first, which came into force on 1 July 2022 was an amendment to Section 32 of the Human Tissue Act 2004 and introduced section 32a. Offences related to financial or commercial dealings in human material for transplant, such as buying or selling human organs now has extraterritorial jurisdiction. The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024 came into force on 1 April 2024. The establishment has raised awareness of these requirements among the renal transplant team. In addition, potential kidney recipients are made aware of this when they sign the consent form to be added to the transplant list.

A sterile suite has been created where the preparation and perfusion of livers may take place to allow the transplant surgeon to assess the organ and if required, to extend the time prior to implantation. In addition, this allows the transplant team to accept two liver offers simultaneously. Whilst one is being transplanted the second liver is placed on the perfusion device to minimise cold ischaemic time. This suite can also be used for the benching of kidneys and therefore has the additional benefit of freeing up theatre space.

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. Criteria CT1 was not applicable as the establishment is not responsible for the activity relating to this assessment criteria.

Review of governance documentation
Procedural documents reviewed relating to licensed activities included: the risk assessment for the continued use of the Microbiology laboratories (following the suspension of their accreditation status due to the postponement of the annual accreditation inspection). The procurement policy demonstrating how the Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002) requirement is complied with, service records for perfusion instruments, record retention policy and certification of the sterile services provider were also reviewed.

Visual inspection
A visit was made to the 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, visits were made to the area where equipment and perfusion fluids are kept by the establishment's National Organ Retrieval Service (NORS) teams, and also to the new area where mechanical perfusion of livers is undertaken as well as benching of kidneys from deceased donors.

Audit of records
The following sets of clinical notes and associated transplant activity records were reviewed:

- Three living kidney donor transplants including one directed donor transplant, one paired/pooled transplant and a non-directed altruistic donor transplant.

- Two deceased kidney donor transplants. One from a donor following circulatory death (DCD) and one from a donor following death by neurological criteria (DBD).

- One simultaneous kidney-pancreas transplant from a DCD donor.

- Two livers retrieved from DCD donors, following normothermic regional perfusion (NRP) and one liver, from a DBD donor, that was placed on a normothermic perfusion machine at the establishment prior to implantation.

- One bowel transplant from a DBD donor.

For the deceased donor organs, electronic documents reviewed during the audit of clinical notes and donor records included: The establishment's operation notes, Transplant Path information including donor serological test results, crossmatch data, donor and recipient blood groups, World Health Organisation (WHO) checklist, results of microbiology sterility checks on the perfusion fluids, recipient consent form, HTA-A form and HTA-B forms.

For the living organ donations, the electronic records reviewed included: The HTA approval, initial serological testing and results from testing prior to the retrieval, and the records of donor suitability decision. The review of the recipient's clinical notes included the establishment's operation notes, transplant record form, donor and recipient blood groups, cross matching records, WHO checklist, the HTA-A form and HTA-B forms (where applicable).

In addition, a selection of incidents were reviewed and discussed with establishment staff.

Report sent for factual accuracy: 14 July 2025

Report returned with comments: 1 August 2025 No factual accuracy or request for redaction comments were made.

Final report issued: 1 August 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 criterion 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.