Site visit audit report
Audit date: 20 and 22 April 2022

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

Although the HTA found that Cambridge University Hospitals NHS Foundation Trust (the establishment) had met the majority of the HTA's assessment criteria that were assessed as part of the audit, one minor shortfall was found against the assessment criteria for donor and organ characterisation.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the audit.

Compliance with HTA assessment criteria

Minor Shortfall

Assessment Criteria	Audit findings	Level of Shortfall
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	The establishment asks potential living donors about current and past intravenous drug use however the responses are not recorded.	Minor

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.	CT4	The establishment uses a mechanical perfusion device, in theatres, to assess the function of donated livers and to extend, if required, the time prior to implantation. The organ characterisation information may be retrieved from the perfusion device by the manufacturer and is backed up to a device maintained by a member of the surgical team. The establishment is advised to consider storing the organ characterisation information on the Trusts' backed-up IT system to help assure the establishment of the retention of the information for the required 30 years.
3.	General	The mechanical perfusion device is currently stored in an area that appeared to be also used as a restroom. The establishment is advised to consider finding a dedicated storage area for the perfusion device.
4.	General	The establishment records the receipt and transfer of organs in a "Transplant Organ, Tissues and Vessels" register. There are instructions printed on the inside cover of this register detailing the organ packing procedure should an organ be sent to another transplant centre. The packing procedures reference the previous style of kidney transport boxes The establishment is advised to add the packing instructions for the new kidney transport boxes to the register.
5.	General	The establishment uses a proprietary electronic patient records system to record most of the clinical information. Some information is still created in paper format which is scanned and added to the electronic system. During the audit, some of the records which should have been scanned and uploaded were not available. The information was subsequently provided. The establishment

Number	Assessment Criterion	Advice
		is advised to conduct periodic audits of the records to ensure that all the information has been uploaded to the electronic system as expected.
6.	General	The establishment maintains a stock of perfusion fluid in 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 monitor the temperature of the storeroom so that it may assure itself that stock is being maintained at the correct temperature.

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 in the Cambridge Transplant Centre.

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, to extend the time prior to implantation. For donors following circulatory death (DCD) and where the establishment is retrieving organs for transplantation, the establishment may undertake normothermic regional perfusion (NRP) where the surgeon can assess the function of the donor organs during the retrieval process. Following NRP, organs are usually transported using static cold storage.

The establishment does not use mechanical perfusion devices when kidneys are received at the establishment, the kidneys remain stored on ice in the transport box before being taken to theatre for implantation.

Since the last audit, the establishment has enhanced the capability of the electronic patient information system with regards to transplantation donor and recipient records.

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 reviewed relating to licensed activities included: accreditation certificates for the Histocompatibility and Immunogenetics (H&I), and histopathology laboratories, and 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, and certification of the sterile services provider were also reviewed.

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

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, 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:

One set of living kidney donor transplant records from an unrelated donor.

One set of deceased donor kidney transplant records from a DCD donor.

One simultaneous pancreas and kidney (SPK) transplant record from a DCD donor.

Two sets of transplant records for liver transplants one from a donor following death by neurological criteria (DBD) and one DCD donor.

Two sets of transplant records for bowel transplants from DBD donors.

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. See minor shortfall and advice and guidance.

Report sent for factual accuracy: 11 May 2022

Report returned with comments: 23 May 2022

Final report issued: 25 May 2022

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the organisation has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Audit Report.

Date: 23 September 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 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.