Virtual regulatory assessment (VRA) and site visit audit report
Audit date 29 and 30 March 2022

Imperial College Healthcare NHS Trust

HTA licensing number 40044

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

Licensed activities – Procurement

Organ type	Kidney
Adult living	**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 – Transplantation

Organ type	Kidney	Pancreas
Adult living	**OC, P, T, I**	
Adult 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

The HTA found that Imperial College Healthcare NHS Trust (the establishment) had met the majority of the HTA's assessment criteria that were assessed during the VRA and site visit. One minor shortfall was found in relation to donor characterisation and organ characterisation.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT3	Potential living donors are asked questions regarding recent tattoos and past or present intravenous (IV) drug abuse, however, the specific responses are not documented on the medical questionnaire.	**Minor**

Advice

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

Number	Assessment Criterion	Advice
1.	P3	The temperature of the fridge used to store deceased donor lymph and spleen is generally recorded, however, there were gaps in the records. The establishment is advised to ensure that the temperature of the fridge is recorded daily.
2.	S1	The review of incidents at the establishment showed that incidents are identified and reported appropriately.

		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.

Background

The establishment has been licensed by the HTA since December 2012. This was the establishment's first VRA combined with a site visit. Before that, two site visit audits of the establishment were conducted; the most recent previous audit took place in October 2017.

Since the site visit in 2017, and as a result of the pandemic, the establishment has reviewed and updated the living donor pathway and made improvements to personalise and stratify the pathway for patients. The establishment is not currently using mechanical perfusion devices for kidneys but intends to do so again in future; a business case for a new machine has been written but this has been delayed by the pandemic. A review of possible alternative mechanical perfusion devices is being undertaken as this may assist when the establishment receives organs from extended criteria donors or multiple offerings.

The establishment is part of a London collaborative with four other establishments. If one establishment cannot guarantee to transplant a named recipient, then the transplant will occur at one of the establishments that has capacity. The recipient will be under the care of the second establishment until discharged. There is an agreed protocol in place and patients are made aware that their transplant may occur somewhere else. The protocol was revisited just before the site visit.

Description of VRA activities undertaken

The HTA's regulatory requirements are set out in Appendix 1 and 3. The following areas were covered during the VRA: discussion on changes to the service since the previous audit, a review of the management of incidents and a review of staff training.

Review of governance documentation
Prior to the VRA, the following documents were reviewed: Establishment's policies and procedures, accreditation certificates for the Histocompatibility and Immunogenetics (H&I) and Microbiology and Pathology laboratories. The audit team also reviewed the certification of the sterile services provider and the records retention policy.

Site Visit inspection

Visual inspection
A visit to the room within the establishment's theatre suite where organs are received, and perfusion fluids are kept, was undertaken. Discussions about monitoring the storage temperature of perfusions fluids were held with staff.

Audit of records
Three sets of cadaveric organ donor records and corresponding recipient clinical notes was undertaken during the audit. These included two kidney transplants and a simultaneous kidney/pancreas transplant. Documents reviewed included a copy of the electronic offering system (EOS) information including donor serological test results, recipient consent form and HTA-B forms.

Two sets of living kidney donors and corresponding adult recipient clinical notes were also reviewed. Donor records reviewed included the HTA living organ donor approval, initial serological testing, results from testing prior to the retrieval and the records of a decision regarding donor suitability. In addition, letters sent to the living donor's GP following discharge and the letters sent to the GP after annual assessments of the donor were seen. The review of the recipient's clinical notes included the establishment's operation notes, transplant record form, cross-matching records and HTA-B forms.

Report sent for factual accuracy: 27 April 2022

Report returned with comments: 11 May 2022

Final report issued: 13 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: 3 February 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 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 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.