Virtual regulatory assessment (VRA) and site visit audit report
VRA: 7 December 2021
Site visit: 9 December 2021

Oxford University Hospital NHS Trust
HTA licensing number 40038

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

Licensed activities – Procurement

Organ type	Kidney	Liver	Pancreas	Small Bowel and modified multivisceral	Composite-abdominal wall	Adrenal gland	Uterus*
Adult (living donor)	**DC, OC, P, T, R**						**DC, OC, P, T, R**
Adult (deceased donor)	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**	**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).

*Establishment has not undertaken any procurement of this organ type.

Licensed activities – Transplantation

Organ type	Kidney	Pancreas	Small Bowel and modified multivisceral	Composite-abdominal wall	Adrenal gland	Uterus*
Adult recipient	**OC, P, T, I**	**OC, P, T, I**	**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).
*Establishment has not undertaken any transplantation of this organ type.

Summary of audit findings

The Oxford University Hospitals NHS Trust (the establishment) was found to have met all HTA assessment criteria that were assessed as part of the VRA and site visit.

Advice

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

No.	Assessment Criterion	Advice
1.	P1	The temperature probe used to record the ambient temperature of the equipment and reagent storage room is positioned between two operational fridges, meaning that the probe is located within a potential 'hot spot' and may record a temperature greater than that of the actual room. The establishment is advised to consider moving the maximum/minimum thermometer to a different location where the room's actual temperature can be more accurately monitored.
2.	P1	The establishment records the temperature of the perfusion fluids, stored in a room at the Theatre Department, once per day as part of the theatre's critical equipment checks. The establishment is

No.	Assessment Criterion	Advice
		advised to consider using a maximum/minimum thermometer to record this temperature so that any temperature deviations that may occur outside of normal operating hours could be detected.

Background

The establishment has been licensed by the HTA since December 2012. This was the establishment's first VRA. Prior to that, two site visits of the establishment had been conducted; the most recent previous site visit audit took place in February 2017.

Since the last audit there have been several changes at the establishment:

- The transplant and renal ward have been relocated to a larger ward.

- The establishment has started a Hepatitis C positive cadaveric donor transplant programme. All potential recipients are given an option to join this programme at the point of listing for transplantation. Additional information regarding the programme is given to patients to inform them of the risks and benefits. Potential recipients can opt-in or out of the programme and their decision regarding this is re-visited, up to and including the point of transplantation.

- The establishment's National Organ Retrieval Service (NORS) team has increased its retrieval activity and now operates a three weeks on and one week off schedule. This is undertaken in conjunction with the NORS team linked to another HTA licensed establishment. In addition, there are eight rather than seven operational teams. This includes three surgeons from the second establishment who are on the NORS rota. There has also been a change in the staff involved in the retrieval service, the lead surgeon is a consultant or senior fellow with other junior surgeons present.

- If theatre capacity or beds are not available, kidney transplants may occur at a second licensed establishment working with the establishment. This agreement works both ways with the possibility of transplants taking place at the establishment if the second organisation does not have sufficient capacity at a particular time. Consultants from both establishment's take part in multidisciplinary team (MDT) and listing meetings.

- A new role of 'perioperative practitioner' has been established These members of staff are trained in the delivery of scrub and perfusion services as well as assisting with retrieval and transplant activities.

- The establishment has been licensed for the procurement and transplantation of the uterus from both living and deceased donors. However, at the time of this audit, no retrieval or transplantation activities have been undertaken.

- The establishment no longer uses sentinel skin flaps to indicate early signs of organ rejection.

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 the changes to the service, a review of five pre-selected incidents and staff training.

Before the VRA, the following documents were reviewed: procedural documents relating to licensed activities, contracts for servicing of perfusion equipment and records of servicing, accreditation certificates for the Histocompatibility and Immunogenetics (H&I) and Microbiology laboratories, reported incidents and adverse events, 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.

Site Visit inspection

A visit to the renal and transplant outpatient area was undertaken. The organ transport boxes, surgical retrieval kits, and perfusion fluids are also kept in this room. Since the last audit, the establishment has introduced monitoring of the temperature of this room using a minimum/maximum thermometer. During the site visit, the temperature reading of this device was observed to be higher than the recommended storage temperature for the fluids kept in this room. The temperature probe, however, is positioned between two fridges which had recently been restocked. Advice was provided to consider repositioning the temperature probe.

Cadaveric donor organs received by the establishment are transferred to the Transplant ward where they are stored in a temperature monitored and locked fridge.

Some additional perfusion fluids are also stored in a fridge in the Theatre Department. Although the temperature of the fridge is monitored this is not undertaken with a minimum/maximum thermometer.

Audit of records

A review of two sets of living kidney donor notes was undertaken. One set was for a directed donor and the second was for a non-directed altruistic donor. The notes reviewed for the directed donation included the health questionnaire completed by the clinical staff, information from the donor's General Practitioner, the reviews by the Consultant Nephrologist, donor consent, virology and other donor/organ characterisation tests. Also reviewed were the notes relating to the MDT discussions for the donor, the HTA authorisation and the HTA-A form.

The retrieval and work-up of the non-directed altruistic donor took place at a different HTA licensed establishment, the records reviewed included the HTA authorisation and virology and other donor/organ characterisation tests.

A review of two sets of organ recipient clinical notes and the associated deceased organ donor files was also undertaken, one for a kidney and one for a simultaneous kidney and pancreas transplant. Records of consent to being registered on the transplant list, copies

of the HTA-A form, details of perfusion fluids used, consent to transplant, copies of the donor information on Electronic Offering System (EOS), the transplant co-ordinator notes, were all present for both cases.

The HTA-B forms are now in an electronic format and located on a secure computer. Only one paper copy of the HTA-B form for one of the deceased donor kidney transplants was available for review.

No anomalies were identified during the VRA. Advice and guidance regarding temperature monitoring was given during the site visit.

Report sent for factual accuracy: 10 January 2022

Report returned with comments: 12 January 2022

Final report issued: 12 January 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 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 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.