Audit report on compliance with licensing assessment criteria
Date: 22 and 23 January 2024

Royal Free London NHS Foundation Trust

HTA licensing number 40025

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

Licensed activities – Procurement

Organ type	Kidney	Liver
Adult (living donor)	**DC, OC, P, T, R**	**DC, OC, P, T, R**
Adult (deceased donor)	**DC, OC, P, T, R**	**DC, 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)

Licensed activities – Transplant

Organ type	Kidney	Liver
Adult recipient	**DC, OC, P, T, I**	**DC, 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

Royal Free London 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.

Advice

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

Number	Assessment Criterion	Advice
1.	CT2	**Kidney and Liver:** The establishment does not ensure that a blood sample is tested for HIV, HBV and HCV at a maximum of 30 days prior to living organ donation. The establishment is advised to ensure that living donor characterisation is undertaken in accordance with guidelines from the British Transplantation Society or The Advisory Committee on the Safety of Blood, Tissues and Organs.
2.	CT2	**Kidney and Liver:** Potential living donors are asked questions regarding medical history and lifestyle, including those about intravenous drug use and travel history. These same questions are discussed with the donors during their living donor medical assessment. The establishment is advised that the medic undertaking the assessment records within the donor's medical suitability summary that these questions have again been reviewed. This is sent to the multidisciplinary team meeting (MDT) for review.
3.	R1	**Kidney and Liver:** The establishment is advised to consider recording that a check has been made to confirm that HTA approval for living donors has been received well in advance of a planned living organ donation.

Number	Assessment Criterion	Advice
4.	CT2	**Kidney:** Potential living NHS donors are asked questions regarding medical history and lifestyle. Living donors from overseas donating in the private sector are not given the same questionnaire as these areas are covered in the donor work up taking place overseas. The establishment is advised to give all potential living donors the same medical history and lifestyle questionnaire to align the donor work ups more closely.
5.	CT4	**Kidney:** Living donor characterisation information gathered as part of the donor work up is summarised and entered into the establishment's electronic patient record system (EPR). Although all information used to determine suitability of the donor is recorded and maintained, there is additional information that is stored in hard copy records only, for example, contemporaneous notes from coordinators. The establishment is advised to scan the hard copy records so that all supplementary information regarding donor work up is available in EPR.
6.	R4	**Kidney:** Upon discharge of a living donor, a letter is sent to the donor's GP. The establishment is advised to consider amending the letter to include a reminder that should the living donor present with any medical conditions which may have an impact for the organ recipient, the establishment is informed so that the recipient can be followed up as necessary. This may facilitate earlier detection of medical conditions that could impact an organ recipient. This is of particular importance in cases of non-directed altruistic and paired/pooled living donations where there is no link between a donor and recipient. The establishment is advised to liaise with the living liver donor team who already have a form of wording in the donor's discharge letter.

Number	Assessment Criterion	Advice
7.	TC1	**Kidney:** The establishment is advised to put in place a procedure through which the HTA-A form number relating to both living and deceased donors is added to the HTA-B forms submission to help facilitate traceability between the donor and recipient.
8.	CT2	**Liver:** During the work up and characterisation of a living liver donor, the MDT requested that a further characterisation serological test was undertaken. However, this test was not ordered. The establishment is advised to develop a procedure through which all requests made at MDT are followed up and results discussed appropriately.
9.	R2	**Liver:** The abdominal retrieval and liver team have a dedicated storage room in the theatre complex where mechanical perfusion equipment and consumables are stored. The establishment is advised to monitor the temperature of this area to help assure themselves that the temperature remains within manufacturer's stated storage temperatures.

Background

The establishment undertakes living and deceased kidney and liver donor transplants. The establishment also has an abdominal national organ retrieval service (NORS) team retrieving both kidneys and livers from deceased donors.

The establishment has been licensed by the HTA since August 2012. This was the establishment's third audit; the most recent previous audit took place in August 2018.

Since the audit in 2018, the establishment has re-started a living liver donor service under its own licence (40025) with guidance from another HTA licensed establishment undertaking similar activity. Additionally, the establishment has greatly expanded the mechanical

perfusion of livers received at the establishment. This allows deceased donor livers to be assessed for longer prior to transplantation. In addition to mechanical perfusion of organs, the NORS team now undertake regional normothermic perfusion during some abdominal organ retrievals. To support this activity, the establishment has recruited a number of new perfusionists who undertake the activity.

In addition, the establishment has started using an electronic patient records system although some documentation remains paper based.

Description of audit activities undertaken

Criteria assessed against during the audit
All HTA assessment criteria apart from CT1, which is not applicable, were reviewed as part of the audit.

Review of governance documentation
As part of the document review, the following were reviewed: Certification relating to the sterile services provider, the Trust's records retention policy, the accreditation certificates for the Histocompatibility and Immunogenetics, microbiology, histopathology and clinical haematology laboratories, the national operating procedure relating to equipment used at the establishment and maintenance records for a perfusion fluid storage fridge and both kidney and liver mechanical perfusion devices.

In addition, eight kidney related and eight liver related incidents, their investigation and any corrective and preventative actions were discussed with the relevant teams.

Visual inspection
The pathway followed when organs are received at the establishment was reviewed including records of receipt. In addition, the area where retrieval kits, perfusion fluids, consumables and mechanical perfusion devices are stored were also visited.

Audit of records
Five sets of clinical records and associated transplant activity for living kidney donor records were reviewed. These were made up of two sets of records relating to NHS patients and three relating to private patients. Three sets of records relating to deceased kidney donor transplants were also reviewed.

One set of living liver donor transplant records were reviewed in addition to two sets of records relating to deceased liver donor transplants.

Records reviewed included: Kidney and liver living donor work-up and characterisation records, donor consent, HTA approval, cross match data, records of blood group checks, medical, surgical and MDT donor suitability sign-off, copies of the electronic offering system forms, the transplant coordinator logs, donor serological test results, medical and social history forms and HTA-A and HTA-B forms.

Report sent for factual accuracy: 19 February 2024

Report returned with comments: 4 March 2024

Final report issued: 25 March 2024

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.