Audit report on compliance with licensing assessment criteria
Date: 30-31 August 2023

NHS Lothian

HTA licensing number 40024

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
Adult (living donor)	**DC, OC, P, T, R**		
Adult (deceased donor)	**DC, OC, P, T, R**	**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	Pancreas
Adult recipient	**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 NHS Lothian (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 assessment criteria for Serious adverse events and reactions (SAEARs).

During the audit, the establishment addressed the shortfall that was identified and updated its documented procedures. As a result, the shortfall was considered to have been met. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA assessment criteria

Minor Shortfalls

Assessment criteria	Audit findings	Level of shortfall
Serious adverse events and adverse reactions (SAEARs) – (these criteria apply to all licensed activities)		
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.	The establishment had a flow chart to illustrate the procedure to follow if a serious adverse event or reaction occurred. However this document did not detail how to report an incident through the on-line reporting portal nor did it stipulate the timeframe in which any serious adverse event or reaction must be reported. *The establishment submitted evidence that the shortfall had been addressed prior to the release of the final report.*	**Minor** ***Fully met***

Advice

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

Number	Assessment Criterion	Advice
1.	CT2	Potential living kidney donors are asked verbally about intravenous drug use by the living donor coordinator and the nephrologist as part of the donor characterisation assessment. However, the

Number	Assessment Criterion	Advice
		form used to collate information during the assessment process only has a field referring to recreational drug use. The establishment is advised to amend the wording on this form to mirror the wording used in the HTA Framework document i.e., 'Past or present history of IV drug abuse'.
2.	CT2	The establishment undertakes normothermic regional perfusion (NRP) during some retrievals from deceased donors. The equipment used to carry out this procedure saves data to a dedicated memory stick. The establishment is advised to download and maintain all data from the perfusion device so that all mechanical perfusion data can be reviewed in the future if necessary.
3.	CT3	Potential living kidney donors are asked about tattoos when undergoing their assessment of suitability to donate. The establishment is advised to consider whether it would be useful to widen these questions to include other cosmetic procedures which involve puncturing the skin ie cosmetic tattooing.
4.	CT4	During a review of donor and recipient clinical notes some examples of incomplete records were found. The first was an incomplete record of organ receipt and another where a hard copy pre-surgical blood group check form had not been completed as expected.. The establishment is advised to consider undertaking periodic reviews of completed paperwork to help assure itself that all documentation is fully completed.

Number	Assessment Criterion	Advice
		In addition, the establishment is advised to consider recording where no perfusion fluid was used prior to implantation rather than leaving the field blank. This may help to distinguish where no fluid has been used rather than the information not being fully completed as expected. Finally, during the review of donor and recipient records, an example of an 'Organ Safety Checklist' form with a mis-transcribed blood group was identified. Following discussions with establishment staff, it was determined that this form is primarily used to alert the theatre department of upcoming transplant procedures and is not used in any way for patient identity checks or other checks, such as blood group checks. The establishment is advised to review the use of the 'Organ Safety Checklist' form and to amend the content so that only essential information is included. In addition, the form contains fields to be signed by the lead theatre practitioner and lead surgeon to acknowledge its review however this practice is no longer taking place. Again, the establishment is advised to review the use of this form and remove the section that is no longer used. .
5.	P3	The establishment maintains records of storage temperatures for perfusion fluids using maximum and minimum temperature probes. On review of these records, instances were identified where the manufacturers upper storage temperature limit had been exceeded. These deviations were believed to be instances where the fridge door had been opened during the removal or replenishment of fluid and therefore did not represent an equipment issue. The establishment is advised to review the temperature monitoring procedure and consider whether a system could be put in place through which transient excursions from the required temperature range can be identified so that the establishment can be assured that the storage temperature has remained suitable in between measurements.

Number	Assessment Criterion	Advice
		In addition, the establishment is advised to monitor the ambient temperature of rooms where other reagents and consumables are stored to help provide assurance that these are being stored in accordance with the manufacturer's specifications.
6.	General	The establishment is advised to consider including a reminder within living donor's discharge letters to GPs regarding any future health issues of the donor that may have consequences for the organ recipient. This reminder may help prompt the donor to alert the establishment of any health conditions that may have relevance to a recipient.
7.	General	The establishment has adopted the National Operating Procedures (NOPs) which document the procedures used at the establishment. The NOPs are supported by various other national procedures and the establishment's own data recording forms, flow charts and other instructional in-house documents. The establishment is advised to append the relevant in-house documents or forms to the relevant NOP so that there is a central resource which describes both the procedures and all supporting documentation.

Background

The establishment undertakes kidney transplants involving living and deceased donors and liver transplants from deceased donors. Although covered by the establishment's license, the establishment was not carrying out living liver donor transplants at the time of the audit.

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 November 2018.

Since the audit in 2018, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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 Trust's medical devices purchasing policy, accreditation certificates for the histocompatibility and immunogenetics (H&I) and histopathology laboratories, the national operating procedures and the national retrieval procedure. As part of the procedural documents, additional documentation used at the establishment to record data associated with the chain of transplantation were also reviewed.

Visual inspection
The pathway following how organs are received at the establishment was reviewed and included the area where organs are received at the establishment. The audit team visited the areas where organs are received and where perfusion fluid and retrieval kits are stored. Finally, the area where equipment is stored ready to be taken on retrievals to carry out NRP, and other mechanical perfusion equipment which is only used at the establishment, was visited.

Audit of records
Records relating to three living kidney donor transplants were reviewed. In one case, the donor workup was reviewed but the transplant has not yet taken place. In relation to the remaining two living donors and recipients, hard copy blood group forms, cross match results, multidisciplinary team (MDT) and surgical suitability sign off records, HTA approval, HTA A and HTA B forms and donor consent records were reviewed.

Reviews were also undertaken of records relating to two simultaneous kidney and pancreas transplants and two kidney only transplants, all from deceased donors. The establishment's transplant checklist paperwork, kidney/SPK checklist, coordinator records, receipt of organ checklist, hard copy blood group form, organ safety checklist, cross match reports, renal transplant data sheet, pancreatic data sheet and HTA A and HTA B forms were reviewed, as applicable, in all cases. One discrepancy was identified on the organ safety checklist regarding a transcription error of the donor and recipient blood groups, see advice and guidance above.

Finally, records relating to three deceased donor liver transplants were reviewed. Transplant coordinator notes, HTA A and HTA B forms, operation notes, donor blood group hard copy forms, organ safety checklists, recipient consent forms and the records of organ receipt were reviewed. No discrepancies were identified.

Report sent for factual accuracy: 29 September 2023

Report returned with comments: No comments received.

Final report issued: 30 October 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 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.