Site visit audit report on compliance with HTA requirements

NHS Greater Glasgow and Clyde

HTA licensing number 40022

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)**

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)**

Under the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

22-23 May 2018

Summary of Audit findings

Although the HTA found that NHS Greater Glasgow and Clyde (the establishment) had met the majority of the assessment criteria, one shortfall was found in relation to retention of records.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

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 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 1: 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.

Licensable activities carried out by the establishment – Procurement activities

Organ type	
Kidney – Adult living	**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)

Licensable activities carried out by the establishment – Transplant activities

Organ type	
Kidney – Adult and paediatric living	**OC, P, T, I**
Kidney – Adult and paediatric deceased	**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)

Background to the establishment and description of audit activities undertaken

NHS Greater Glasgow and Clyde (the establishment) carries out living and deceased donor kidney transplants into both adult and paediatric recipients. The establishment also procures kidneys from adult living donors.

Procurement and transplant activities for adult patients take place at the Queen Elizabeth University Hospital (QEUH) in Glasgow, while paediatric transplants are carried out at the Royal Hospital for Children. The two hospital buildings are adjacent to each other and are connected through internal corridors.

Donor testing as part of donor characterisation is carried out by the establishment's laboratories, which hold Clinical Pathology Accreditation (CPA) or United Kingdom Accreditation Service (UKAS) accreditation. Tissue typing, virtual and wet cross-matching takes place at the establishment's Histocompatibility and Immunogenetics (H&I) laboratory at the Gartnavel Hospital site, which holds CPA and European Federation for Immunogenetics (EFI) accreditation. Microbiology testing, including mandatory tests for HIV, HBV and HCV, is carried out at a laboratory at another site within the establishment, which is accredited by UKAS (ISO 15189:2012). Histopathology services are provided at the QEUH site by a laboratory holding CPA.

Deceased donor organ pathway

Offers of deceased donor organs for adult recipients are received by transplant coordinators, who review the donor characterisation information using the Electronic Offering System (EOS) and inform the on-call transplant surgeon of the offer. The surgeon makes the decision on whether to accept or reject the offer.

Offers of deceased donor organs for paediatric recipients are received by the paediatric on-call nephrologist, who reviews EOS and discusses the offer with a transplant surgeon and paediatric urologist.

Organs arrive at either the adult ward 4C, or the paediatric ward 3C depending upon the intended recipient. A ward ledger is in place in each ward where receipt of the organ is recorded. Samples for cross-matching are sent to the H&I laboratory via a contracted taxi company; if a wet cross-match is required this is done immediately, however, if the transplant can proceed on a virtual cross-match, samples are sent the following day and are kept in fridges on either ward overnight.

The organ is transferred to theatres, adult or paediatric, by the implanting surgeon after signing the ward ledger to confirm the organ has been collected. In theatre, the surgeon assesses the organ prior to implantation. A surgical safety checklist is used by the team and as part of this checklist, the donor identification details are checked against the cross-match and blood group paperwork.

If an organ cannot be transplanted into the intended recipient, and needs to be transported to a different transplant centre, the organ is packaged in accordance with current practice (see *Advice*, item 4).

Living donation pathway

Retrieval of kidneys from adult living donors is carried out at the QEUH. Prospective donors are assessed through a multi-step process where they initially meet with a living donor coordinator, who takes their medical history and arranges for the initial characterisation tests to be performed. The donor is subsequently seen by a nephrologist and a transplant surgeon. The establishment has a checklist in place within their renal patient database that details the

steps that need to be completed as part of the donor characterisation process. The process includes testing for infections, including the mandatory tests for HIV, hepatitis C and hepatitis B. The establishment stated that their procedure is to repeat these tests two weeks prior to donation; however, in one case observed during the audit, these tests had not been repeated within the 30 days before donation as per national guidance (see *Advice*, item 1). Donors are also asked about their lifestyle, including past or present use of intravenous drugs.

Once the team is satisfied that a prospective donor is suitable to donate, the donor is referred to an Independent Assessor. When HTA approval has been obtained, theatre time is booked.

A surgical safety checklist is used by the team and, as part of this checklist, the donor and recipient identification details are checked against the cross-match and blood group paperwork.

Perfusion fluid is stored in a number of locations throughout adult and paediatric theatres. Some fluid is stored in fridges, and a larger stock supply at room temperature. Not all of the storage locations are temperature monitored (see *Advice*, item 2).

The establishment takes part in the paired/pooled scheme for living kidney donors. Kidneys that are sent to other centres are packaged in accordance with European practice (see *Advice*, item 4) and transport is arranged via NHS Blood and Transplant (NHSBT). Kidneys for implantation into paediatric recipients are transferred from adult theatres to paediatric theatres by the implanting surgeon.

Living donors are followed up initially by the establishment, and subsequently via their own GP upon formal discharge from the establishment's care. On discharge, a letter is sent to the donor's GP explaining the requirement for yearly follow-up and what checks should be undertaken. The letter includes a request that the GP reports any health issues the donor incurs, such as malignancy or infection, that may have an impact for the recipient of the donor organ.

For donors who are not resident in the UK, the establishment assesses their access to medical care in their home country before agreeing that the donation can go ahead. A letter with follow-up instructions, similar to that sent to the GP of donors living in the UK, is sent overseas to the donor's medical professional. This letter is translated into the donor's native language if required.

Tour of the facilities and roundtable discussions

The audit team visited the areas where different activities under the licence take place, following the organ pathway. This included visits to the adult renal ward and theatres, and the paediatric renal ward and theatres, as well as the H&I laboratory at the Gartnavel site. Three roundtable discussions were held to discuss all activities taking place under the licence. These were attended by staff involved in the different activities carried out under the licence.

Document review

The audit team carried out a document review, which included patient records as well as procedural documents and accreditation certificates. Patient records relating to three living donors were reviewed, as well as records for five organ recipients.

The accreditation status of the laboratory services used for donor characterisation were reviewed and found to be suitable.

The establishment does not have a policy relating to the procurement of medical devices that specifies compliance with the Medical Devices Regulations 2002; however, the team received

confirmation from senior staff in the establishment's procurement department that the establishment complies with these regulations.

Local adaptations of the National Operating Procedures (NOPs) and NHSBT's SOP3888 were reviewed (see *Advice*, item 7).

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
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.	Although the local adaptation of "NOP006 – Transfer and storage of donor and organ characterisation information and storage of traceability data" is clear on the requirement to keep records relating to donor and organ characterisation for 30 years, the establishment's overall policy states that records will be destroyed within three years of a patient's death, or six years after their last contact with the establishment. This policy would override the local adaptation of the NOP and therefore there is a risk that records relating to donor and organ characterisation that must be kept for 30 years are destroyed.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	While all living donor records observed contained the information specified in Part A of the Annex to the Directive, one living donor reviewed had not had testing for HIV, Hepatitis B or Hepatitis C repeated within the 30 days before donation as recommended by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in their publication "Microbiological Safety Guidelines", paragraph 6.5. However, staff told us that it is standard practice to test all donors in the two weeks prior to the donation. The establishment is advised to review their practice to help assure themselves that they always undertake activity in accordance with this guidance.
2.	P1	The establishment is advised to review the temperature monitoring arrangements of perfusion fluid storage, as not all locations where fluid is stored are temperature monitored.
3.	P1	The establishment is intending to start using an *ex vivo* perfusion device in the near future. The establishment is advised to seek confirmation from the manufacturer that the new device's CE marking covers the intended use.

No.	Assessment Criterion	Advice
4.	TP1	While staff at the establishment correctly explained the process for packaging an organ for transportation using three bags, the local adaptation of "NOP003 – Packaging, labelling and transport of organs from deceased and living donation and transplantation" is not in line with European practice of using three bags to package the organ. The NOP has not been updated to reflect the most up-to-date version published by NHSBT. The establishment's training and competency package was also found to be out of date with regards to packaging of organs. The establishment is advised to update the local version of NOP003 as well as their training and competency package to ensure that this aligns to European practice.
5.	TC1	On one occasion observed, where an organ was retrieved in adult theatres and subsequently moved to paediatric theatres, the HTA-A form number had not been transferred to the HTA-B form. Although there are other points of data linking the donor with the recipient in this case, there is a risk that the record of traceability is incomplete. The establishment is advised to review their procedures to ensure that the HTA-A form number is always transferred across to the HTA-B form, especially in cases where the organ moves from adult to paediatric theatres.
6.	S1	While the establishment has a local adaptation of SOP3888 in place for reporting incidents to NHSBT, this document has not been updated to reflect the current version of SOP3888 published by NHSBT. The establishment is advised to review their local version to ensure that it remains appropriate and reflects the current requirements.
7.	General	The establishment is advised to review all local adaptations of the National Operating Procedures (NOPs), as these were last updated in 2012. The NOPs published by NHSBT have been updated since 2012, and there is a risk that the establishment's local procedures are not in line with national practice.

Concluding comments

The establishment exhibited good practice in a number of areas. The database used for managing patient data contains a checklist to ensure that all required information has been obtained before donation or transplant can go ahead. All living organ donors are provided with a wallet-size card that confirms that they have donated a kidney, and details the yearly follow-up tests that they require.

There are some areas of practice that require improvement, including one minor shortfall in relation to record retention. The HTA has given advice to the establishment with respect to microbiology testing, storage of perfusion fluid, use of *ex vivo* perfusion devices, completion of mandatory forms and updates to documented procedures.

The HTA requires that the establishment addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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.

Report sent for factual accuracy: 20 June 2018

Report returned with comments: 4 July 2018

Final report issued: 10 July 2018

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: 30 June 2020

Appendix: 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 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** 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 both the draft and final audit report. You 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 audit

 a request for information that shows completion of actions

 monitoring of the action plan completion

 follow up at next desk-based or site-visit audit.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.