Site visit audit report on compliance with HTA requirements

Birmingham Women's and Children's NHS Foundation Trust

HTA licensing number 40051

Licensed for

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

- **<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 Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014

28-30 August 2019

Summary of Audit findings

Birmingham Women's and Children's NHS Foundation Trust (the establishment) was found to have met all relevant assessment criteria. The HTA has given advice to the establishment with regards to temperature monitoring of perfusion fluids and documentation.

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 – Transplant activities

Organ type	Kidney	Liver	Small Bowel
Paediatric deceased	**OC,P, T, I**	**OC,P, T, I**	**OC,P, T, I**
Adult living	**OC,P,T, I**	**OC,P, T, I**	**OC,P, T, I**
Adult deceased	**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)

Background to the establishment and description of audit activities undertaken

Birmingham Women's and Children's Hospital NHS Foundation Trust (the establishment) has been licensed by the HTA since August 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

The establishment carries out kidney, liver and small bowel transplants in paediatric patients. The small bowel programme includes multi-visceral and modified multi-visceral transplants. Live donor kidney and liver transplants are performed at the establishment. However, live donor work up and organ retrieval surgery takes place at another HTA licensed establishment.

Tissue typing and cross-matching for the establishment are performed by a nearby histocompatibility and immunogenetics (H&I) laboratory which has both United Kingdom Accreditation Service (UKAS) accreditation and European Federation for Immunogenetics (EFI) accreditation.

Equipment used during transplants is CE-marked and meets the requirements of the medical devices regulations. The establishment has a national operating procedure, which mandates that all equipment that is purchased is compliant with the requirements of the medical devices regulations. In addition, written confirmation that only CE marked equipment is purchased by the Trust was received.

Perfusion fluids are stored in a fridge in theatres. The temperature of the fridge is monitored and recorded daily.

Medical activities being undertaken at the establishment are performed under the advice and guidance of a registered medical practitioner (RMP). Healthcare staff directly involved in the chain from donation to transplantation are suitably qualified and are provided with training necessary to perform their tasks.

During the audit, the auditors followed the pathway of organs received into the hospital for transplantation. Policies and procedures, and samples of transplant patient clinical records were reviewed. Roundtable meetings with staff involved in transplantation also took place.

Cadaveric Donor Transplants

Kidney transplants

Organ offers from NHSBT Hub Operations are received by the on-call nephrologist who uses the donor and organ characterisation information in NHSBT's electronic offering system (EOS) to assess the offer for its suitability. If the organ offer is suitable for the recipient to whom it has been offered, the nephrologist passes the donor details to the implanting surgeon who also reviews the donor and characterisation information in EOS.

If determined to be suitable, the nephrologist contacts the H&I laboratory who advise on the type of cross match required. Once completed, the coordinators from the donor hospital alert the transplant team about associated timings and provide updates on donor and organ characterisation. The delivery address for the organ is pre-arranged by the establishment. Organs can either be received at Ward 1 in the hospital or taken directly to theatres. Kidneys that arrive before midnight are often transplanted on the evening of receipt. If the organ is received after midnight, it will be transplanted the following morning.

The date and time of receipt of the kidney are recorded in a logbook. Staff verify the details given about the donor against the paperwork to assure themselves that the correct kidney has been received.

If the kidney was delivered to Ward 1 in the hospital, the surgeon collects the kidney and takes it to theatre. Once the kidney is in the theatre, it is inspected by the implanting surgeon. The implanting surgeon checks the donor's blood group using the hard copy of the donor blood group paperwork and reviews the HTA-A form which accompanies the organ. The surgeon cross matches these details with those of the expected donor details obtained from EOS, prior to the kidney being implanted.

A sample of transport fluid that surrounds kidneys is sent to the microbiology laboratory in the hospital for analysis. The establishment informs ODT Hub Operations if any microorganism is detected in the transport fluid.

Following implantation, the surgeon completes all necessary paperwork. All paperwork is stored in a secure location and relevant forms are returned to NHSBT within the required 7 days. The establishment has received training and in the future will be completing the HTA-B form details via an online portal.

Liver, Bowel and Multi-visceral transplants

The organ offer comes via NHSBT Hub Operations for a named patient. The transplant surgeon reviews EOS and accompanying information. If bowels are being retrieved for a recipient at the establishment, a surgeon from the establishment joins the National Organ Retrieval Service (NORS) team to undertake the organ retrieval at the donor hospital.

The transplant coordinator will liaise with the transplant team at the establishment regarding progress of the procurement and estimated timings. Once the condition of the organ is confirmed as suitable, the transplant team at the establishment will start to prepare the recipient for transplant.

If an organ is offered for a liver only transplant, the transplant team is notified of the offer by NHSBT Hub Operations via SMS text. The surgeon reviews EOS and makes the decision on the suitability of the organ offer. If accepted, arrangements are made for transport. The liver will be delivered directly to theatres and relevant information is recorded in the theatre delivery record book and an organ donor characterisation checklist.

If a decision is made by the surgeon to split the liver, the surgeon will pack the split liver intended for implantation by another transplant centre in the same box that it arrived in and complete a split liver form. This form will accompany the liver to its destination. Transport is arranged by NHSBT or the recipient centre receiving the split liver.

After completion of the transplant, relevant forms are completed by transplant staff and sent to NHSBT within the required 7 days.

Living Donor Transplantation

The process regarding receiving organs from living donors is very similar to the cadaveric pathway. Identification and work up of living donors takes place at another HTA licensed hospital. Once retrieved, the organ is transported to the establishment for implantation as described in the above sections of the report.

Audit of clinical notes and document review

The audit of the establishment's licence included an audit of recipient clinical notes and where possible, information from the relevant donor files. A review of files was undertaken in relation to the following cases:

- Three living kidney transplants
- Three cadaveric kidney transplants
- Two living liver transplants
- One combined liver/bowel transplant and one multi-visceral transplant
- One cadaveric split liver and one cadaveric whole liver transplant

In all of these cases, where applicable, the following records were reviewed:

- Consent for transplant
- Organ delivery forms
- Organ and donor characterisation checklist
- Record of transplant timings
- Operation notes
- Copy of EOS records

- Hard copy donor blood group forms
- HTA-A and HTA-B forms
- Records of perfusion fluids/batch numbers used
- HTA approval form

No anomalies were identified during the review.

The establishment's laboratory that undertakes testing of the kidney's transport fluid and the pathology lab is accredited by UKAS and EFI. The current accreditation certificates were reviewed during the audit. In addition, documentation demonstrating that the establishment's sterile services provider met the requirements of the assessment criteria was reviewed during the audit and was found to be satisfactory.

The establishment has documented procedures in place for the management of serious adverse events and reactions both internally and those that need to be reported to NHSBT.

The HTA audit team also reviewed the establishment's operating procedures and surgical checklists.

Advice

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

No.	Assessment Criterion	Advice
1.	P3	The establishment is advised to update the lower temperature limit on the fridge where perfusion fluids are stored to reflect manufacturer's required storage conditions.
2.	I1	The operation policy for renal transplant should reflect the practice of the implanting surgeon checking the donor and organ checklist details prior to implantation of the organ.
3.	I1	The establishment is advised to consider putting a checklist in the transplant packs to detail the paperwork that would be included in the packs. This may help to identify if any of the expected information has not yet been filed.
4.	TC3	The establishment is advised to consider scanning the pages of the receiving organ tissue logbook so that records of receipt are backed up.

Concluding comments

The transplant activities are undertaken by a team of surgeons and supported by dedicated staff within the theatres, clinics and associated laboratories.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent for factual accuracy: 25 September 2019

Report returned with comments: 15 October 2019

Final report issued: 18 October 2019

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.

HTA assessment criteria

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.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.
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 CPA or UKAS accreditation.
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), 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), 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 paragraph 68 of the framework document, 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 Directive 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 framework document are verified prior to proceeding to implant an organ.
I3) Where any of the information specified in Annex A of the Directive 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.