Site visit audit report on compliance with HTA requirements

University Hospitals of Leicester NHS Trust

HTA licensing number 40054

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 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

09 October 2018

Summary of Audit findings

University Hospitals of Leicester NHS Trust (the establishment) was found to have met all relevant assessment criteria.

The HTA has given advice to the establishment with respect to temperature monitoring 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 – 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	**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

University Hospitals of Leicester NHS Trust is a single organ centre (kidney) and 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.

All transplant activity takes place at the establishment and involves adult patients only The establishment does not provide services to the National Organ Retrieval Service (NORS).

Tissue typing and cross-matching are performed at the histocompatibility and immunogenetics (H&I) laboratory based in the hospital.

All laboratories undertaking donor and organ characterisation assessments are appropriately accredited by a relevant body. The H&I laboratory at the establishment has United Kingdom Accreditation Service (UKAS) accreditation. The microbiological, pathology and virology testing laboratory, which is also located at the establishment, provides services to support transplant activities and is accredited by UKAS.

During the audit, the audit team followed the pathway for a cadaveric donor kidney received by the hospital for transplant. Policies, procedures and samples of transplant patient records were reviewed. Round-table meetings with staff involved in transplantation also took place.

Living Donor Kidney Transplants

The establishment has a living kidney donor program through which adult donors can donate a kidney to adult recipients. Potential donors come forward to the establishment during a recipient's medical review or may be referred to the establishment by other transplant centres. The establishment also receives a number of enquiries from potential non-directed altruistic donors.

The establishment carries out its own donor characterisation of living donors. The Living Donor Coordinator (LDC) provides information to potential donors on the risks associated with living donation. The LDC in conjunction with Registered Medical Practitioners (RMPs), undertake a thorough assessment of the potential living donor. All assessments are documented in the donor's clinical notes.

Once all of the donor characterisation assessments are completed and signed off by the Nephrologist and Consultant Surgeon, the case will be referred to the Independent Assessor (IA). Independent translators are provided when required.

The LDC arranges for tissue typing of potential donors and cross matching to assess compatibility with the recipient.

The Consultant Surgeon checks that consent for retrieval is in place before the procedure commences. The retrieving surgeon is responsible for reviewing the information in the donor notes before retrieval. Transplants take place within any of the available theatres within the hospital.

Perfusion fluid is stored in a temperature monitored fridge and at room temperature near theatres.

The Consultant Surgeon completes the HTA-A and HTA-B forms. These forms are checked by the nursing staff and the LDC sends the forms to NHSBT within 7 days.

Equipment used during transplants is CE-marked and meets the requirements of the medical devices regulations. The establishment has a standard operating procedure, which mandates that all equipment that is purchased must be compliant with the requirements of the medical devices regulations.

Medical activities being undertaken at the establishment are performed under the advice and guidance of a 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.

Following the transplant, the donor and recipient stay in the hospital for a period of time and are monitored by the Consultant Transplant Surgeon at two weeks, three months and then on an annual basis post-surgery. Should the patient after a year choose to be followed up by the GP, the transplant team has set up to collect and monitor data (BP/Urine for protein/bloods). The establishment carry out on-going monitoring and follow up of the donor. A discharge letter is given to the donor's GP informing them to contact the centre if anything untoward happens to the donor which may have an impact for the recipient.

Deceased Donor Kidney Transplants

Organs are delivered directly to the transplant unit and placed in a locked cupboard. A member of staff will check the packaging and paperwork including identification details and record information on a kidney tracking form which stays with the kidney. Registrars then collect the kidney and it is taken to theatres immediately. Any associated material (spleen and lymph nodes) is removed and collected by laboratory staff.

The implanting Surgeon checks the EOS blood group, the HTA-A form that accompanies the organ and cross match details prior to the kidney being implanted.

A sample of transport fluid that surrounds kidneys from cadaveric donors is sent to the microbiology laboratory for analysis. The establishment will inform ODT Hub Operations if any microorganism is detected in the transport fluid.

Audit of clinical notes and document review

During the establishment's audit, a review of the following was undertaken by the audit team:

- Four sets of living kidney transplant recipient clinical notes and associated donor files
- Files relating to four deceased kidney transplants; and

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

- HTA-A and HTA-B forms
- Medical questionnaire
- Records of perfusion fluids/batch numbers used
- HTA approval form and referral letter
- Consent for donation
- HLA typing
- Blood test results
- Discharge letter

The HTA audit team also reviewed the establishment's operating procedures, surgery checklists and accreditation certificates from laboratories.

Compliance with HTA assessment criteria

All applicable assessment criteria were fully met.

Advice

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

No.	Assessment Criterion	Advice
1.	CT3	The establishment is advised to include behavioural risks such as tattoos and skin piercings in the medical questionnaire when undertaking characterisation assessments of potential living donors.
2.	P1	The establishment is advised to monitor and record ambient room temperatures where perfusion fluid is stored to help assure itself that perfusion fluids have not been exposed to any deviations in temperature outside of the manufacturer's recommended storage temperature range. *During the audit, establishment staff put procedures in place to monitor and record temperatures*.
3.	General advice	The establishment is advised to review the kidney donor tracker document forms regularly to help assure itself that the forms are being completed appropriately.

Concluding comments

The transplant activities are undertaken by a team of surgeons and supported by dedicated staff within the transplant ward, theatres and associated laboratories. The service is consultant led and the consultant surgeon is involved in all surgical transplant procedures, either as principal or assisting surgeon when overseeing procedures carried out by specialist trainees. There is good communication between all staff on site.

The HTA has given advice to the establishment with respect to temperature monitoring and documentation.

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

Report sent for factual accuracy: 31 October 2018

Report returned with comments: 02 November 2018

Final report issued: 13 November 2018

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.