Site visit audit report on compliance with HTA requirements

Nottingham University Hospitals NHS Trust

HTA licensing number 40017

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

26-27 March 2019

Summary of Audit findings

Nottingham University Hospitals NHS Trust (the establishment) was found to have met all relevant assessment criteria with the exception of one minor shortfall in relation to the accreditation of the cellular pathology lab. The HTA has also given advice to the establishment.

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**
Paediatric	**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

Nottingham University Hospitals NHS Trust (the establishment) is a single organ transplant centre 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.

The establishment carries out living and deceased donor kidney transplants. Adult transplants are undertaken at City Hospital and paediatric transplants are undertaken at Queen's Medical Centre.

The establishment carries out approximately 90 transplants annually, mostly deceased donor kidneys, the remainder being living donor kidney transplants.

Tissue typing and cross-matching for the establishment are performed by another histocompatibility and immunogenetics (H&I) laboratory in a nearby hospital which has United Kingdom Accreditation Service (UKAS) accreditation. The establishment does not participate in the National Organ Retrieval Service (NORS).

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 is 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 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 adult and paediatric kidneys received into the City Hospital and Queen's Medical Centre respectively for transplantation. Policies, procedures and samples of transplant patient clinical records were reviewed during the audit. Round-table meetings with staff involved in adult and paediatric transplantation also took place.

Living Donor Kidney Transplants

Potential kidney donors refer themselves to the establishment.

Once a suitable potential donor is identified, an initial assessment is completed and information is given to them by the living donor co-ordinator (LDC).

Information given to potential donors includes the potential risks associated with living donation. The LDC in conjunction with RMPs, arrange appointments so that the potential donors can attend clinics where donor and organ characterisation assessments can take place. All assessments are documented in the donor's clinical notes and discussed at multi-disciplinary team (MDT) meetings.

Once all 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).

The consultant surgeon checks that consent is in place before the organ retrieval surgery commences. The retrieving surgeon is responsible for reviewing the information in the donor notes prior to retrieval.

Perfusion fluid is stored in a fridge in theatres and the temperature is checked and recorded daily. Perfusion fluid stock is also stored at room temperature.

The consultant surgeons involved in retrieval and transplantation complete the HTA-A and HTA-B forms respectively in conjunction with the nursing staff. Once the forms are completed and checked by the nursing staff, they are sent to the data department in the hospital where they are scanned into the computer system and sent to NHS Blood and Transplant (NHSBT) within 7 days.

Following the transplant, the donor and recipient remain in hospital for a period of time and are monitored by the consultant transplant surgeon and nephrologist regularly during this time. The establishment makes arrangements for on-going monitoring and follow up of the donor. If the donor wishes to be returned to the care of their general practitioner (GP), a discharge letter is sent to the donor's GP.

Deceased Donor Kidney Transplants

Offers of deceased donor kidneys are received directly at the transplant unit at City Hospital by transplant staff for adult and paediatric transplants. The offer is discussed with the on-call transplant surgeon who has access to the Electronic Offering System (EOS) and makes the decision whether to accept or reject the organ being offered. If an offer is accepted, the recipient coordinator contacts NHSBT who arrange the transport.

For adult transplants, organs are delivered to nursing staff on the renal ward and placed in a secure room. For paediatric transplants, the driver delivers the organ to the nurse in charge at Queen's Medical Centre.

A member of staff will check the packaging and paperwork including the donor identification details. These checks are recorded using a checklist for accepting deceased donor kidneys. If the kidney is not taken to theatres immediately, staff check the ice levels and replenish when necessary.

The implanting surgeon checks the donor's blood group using the hard copy donor blood group form and reviews the HTA-A form that accompanies the organ. The surgeon cross matches these details with those of the expected donor obtained from EOS prior to the kidney being implanted.

A sample of transport fluid that surrounds kidneys is sent to the microbiology laboratory for analysis. The establishment informs 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 in relation to adult and paediatric cases:

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

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

No anomalies were identified during the review.

The HTA audit team also reviewed the establishment's operating procedures, surgical checklists and accreditation certificates from the relevant laboratories and sterile services department.

Compliance with HTA assessment criteria

No.	Assessment Criterion	Level of shortfall
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA or UKAS accreditation.		
CT5	Although the majority of histological analysis of tissues is undertaken during cadaveric organ retrieval, the establishment may send tissue samples from organs for histological analysis locally upon receipt of an organ. The cellular pathology laboratory that is used for donor and/or organ characterisation does not have current UKAS accreditation. The use of this laboratory has not been formally justified nor has the accreditation status been reviewed on a regular basis as noted in paragraphs 40-42 in the HTA Framework document - Quality and Safety of Organs intended for Transplantation (updated November 2016). *Satisfactory information has been received from the establishment and the HTA considers the shortfall to have been met.*	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	The establishment is advised to ensure that living donor characterisation is undertaken in accordance with British Transplantation Society (BTS) or The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) guidelines. Currently the unit does not routinely ensure that a blood sample is tested for HIV, HBV and HCV at a maximum of 30 days prior to organ donation.
2.	CT3	The establishment is advised to review SABTO and BTS guidance and consider whether it may be useful to add additional questions to the potential live donor questionnaire, such as questions relating to tattoos and piercings.
3.	P1	The establishment is advised to monitor and record ambient room

No.	Assessment Criterion	Advice
		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.
4.	R4	The establishment is advised to include, in the annual follow up letter to the GP, a reminder to contact the unit should the living donor present with any medical conditions which may have a potential consequence for the organ recipient.
5.	I1	The establishment is advised to remind staff about completing the pathway document for deceased donor transplants once they have reviewed EOS. The establishment should also consider adding a field to record sign off that EOS has been reviewed by the implanting surgeon within the paediatric transplant pathway document.
6.	General advice	The establishment is advised to review their NOPs with a view to adapting them to reflect local procedures where necessary. For example: • NOP 6 should be adapted to reflect that the data team return the HTA- A and HTA-B forms to NHSBT • NOP 3 should be adapted to reflect the practice of using coloured slings around the organ transport bag to identify whether it is the left or right kidney • Where additional information is used to support procedural documents, these could be appended to the relevant NOPs (i.e. living donor pathway).

Concluding comments

The transplant activities are undertaken by a team of surgeons and supported by dedicated staff within the theatres, clinics and associated laboratories. During the audit, good communication and a strong working relationship between all establishment staff was observed.

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: 23 April 2019

Report returned with comments: 3 June 2019

Final report issued: 4 June 2019

Audit CAPA Plan Closure Statement:

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: 10 June 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.