Site visit audit report on compliance with HTA requirements

Belfast Health and Social Care Trust

HTA licensing number 40046

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

9-10 May 2018

Summary of Audit findings

Belfast Health and Social Care Trust (the establishment) was found to have one minor shortfall in relation to testing and information provided on the donor medical questionnaire.

The HTA has given advice to the establishment with respect to 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**
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

Belfast Health and Social Care Trust is a single organ centre (kidneys) 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. Transplant activity takes place at two hospital sites within the Trust.

Procurement of kidneys from living adult donors, and implantation of kidneys for adult recipients, takes place at Belfast City Hospital. Implantation of kidneys for paediatric recipients takes place at Belfast Hospital for Sick Children.

Kidneys from deceased donors, and kidneys from non-directed altruistic living donors where procurement takes place elsewhere, are transported to Belfast City Hospital. All kidneys for paediatric recipients are first sent to Belfast City Hospital and then transported to the Hospital for Sick Children using hospital transportation. Donor and organ characterisation, testing, and, where necessary, histopathology on donor kidneys, is performed by the establishment. The establishment does not provide services to the National Organ Retrieval Service (NORS).

The establishment has adopted all of NHS Blood and Transplant's (NHSBTs) National Operating Procedures (NOPs), adapted them to reflect local practices, and amalgamated them into a single overarching document, 'The Quality and Safety of Organs Intended for Transplantation'.

All laboratories undertaking donor and organ characterisation assessments are appropriately accredited by a relevant body.

During the audit, the auditors followed the pathway of a kidney received into Belfast City Hospital and its transfer and arrival to the Hospital for Sick Children. Policies and procedures, and a sample of transplant patient records were reviewed. Round-table meetings with staff involved in transplantation took place.

Living Donor KidneyTransplants

Potential transplant candidates are often identified as part of their clinical assessment and the discussion about living donation happens early in the patient's clinical history. The establishment carries out its own donor characterisation of living donors for adult and paediatric patients. The Living Donor Co-ordinator (LDC) provides information to potential donors on the risks associated with living donation. Once identified as a potential donor, the LDC, in conjunction with Registered Medical Practitioners (RMPs), undertake a thorough assessment and arrange for potential donors to attend a one-day assessment. The assessment is documented in the donor's medical records.

Patient information is recorded on a form, which is kept in the patient notes. 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). Independent translators are provided when required.

The LDC arranges for tissue typing of potential donors and cross matching to assess compatibility with the recipient. Tissue typing and cross matching takes place at the Histocompatibility and Immunogenetics Laboratory (H&I Lab) which has United Kingdom Accreditation Service (UKAS) accreditation and is located at the hospital. The microbiological and virology testing laboratory, which is also located at the establishment, provides services to support transplant activities and is also accredited by UKAS.

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 in dedicated theatres within the hospital.

Perfusion fluid is stored in two locations: (1) a temperature monitored fridge next to the theatre where staff check the temperature and stocks daily; (2) a securely locked room where fluid is stored at room temperature.

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 for a period of time in the hospital and are monitored by the Consultant Nephrologist regularly during this time. The establishment makes arrangements for on-going monitoring and follow up of the donor. A discharge letter is given to the donor.

Deceased Donor Kidney Transplants

During working hours, the Transplant Coordinator receives the kidney offer from ODT Hub Operations and discusses the offer with the Consultant Surgeon. The nurse on the renal ward receives the kidney offer out of hours. If the organ is for a paediatric recipient, then the case is discussed directly with the Paediatric Consultant Nephrologist.

Staff follow a step-by-step guidance sheet from the point of kidney offer through to transplantation.

All cases are initially discussed with the Surgeon and if a decision is made to accept, the transport is arranged by ODT Hub Operations. Organs are delivered directly to the renal ward and placed in a dedicated locked room. Two members of staff will check the packaging and paperwork including identification details. They also check ice levels on arrival and then every four hours.

The spleen and lymph nodes that accompany the kidney are either put into a temperature monitored fridge if delivered out of hours for next day collection, or collected immediately by the H&I Lab. The spleen and lymph nodes are accompanied by their own form. In addition, a chain of custody book is filled out by staff.

If more than one kidney is received at a time, a sticker from the chain of custody book is placed on the organ boxes to alert staff. The implanting Surgeon checks the electronic offering system (EOS), blood group, the HTA-A form that accompanies the organ and cross match details prior to the kidney being implanted.

The kidney is taken directly to theatre or put into a securely locked cupboard until required. A sample of transport fluid that surrounds kidneys from deceased 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.

The establishment has two perfusion devices which are clearly labelled to distinguish one from the other and Surgeons are trained in the use of the devices. When used, they are checked hourly and details recorded.

There are regular multi-disciplinary team meetings where decisions made to accept or reject organs are reviewed.

Audit of clinical notes and document review

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

- three sets of living kidney transplant recipient clinical notes and associated donor files
- files relating to three deceased kidney transplants; and
- files relating to two paediatric 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

The HTA audit team also reviewed several operating procedures, surgery checklists, accreditation certificates from laboratories, and incidents. No discrepancies were identified.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
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.	The establishment does not ensure that donor characterisation is in line with British Transplantation Society or The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) guidelines as the unit does not ensure that a blood sample is tested for HIV, HBV and HCV within 30 days (before organ donation). The medical questionnaire for living donors does not contain questions about behavioural risks such as piercings, tattoos, and sexual behaviours.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	P1	During the audit it was noted that the temperature of the room where perfusion fluid is stored was not regularly monitored or recorded. Staff are advised to monitor and record the temperature to ensure the fluid is kept within required temperatures. *During the audit the HTA was informed that this is now being monitored and staff assured the audit team a record will also be kept.*
2.	TP1	The establishment is advised to amend their overarching document, 'The Quality and Safety of Organs Intended for Transplantation' to reflect current practice, specifically: • Change the reference from 'double bagging' of a kidney to 'triple bagging' on pages 10 and 12 • packing details are not included in Appendix 12 from NOP 3
3.	General advice	The decontamination of re-usable medical devices document is out of date and should be reviewed and updated.

Concluding comments

Areas of good practice were observed during the audit. Some of these are included below:

- The establishment has clear forms which ensure traceability. Records reviewed by the audit team showed that these forms have been audited and adapted to make them more user friendly over time;

- There is a good working relationship between paediatric and adult services.

One minor shortfall was found in relation to donor testing and information on the medical questionnaire. The HTA has given advice to the establishment with respect to documentation.

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

Report sent for factual accuracy: 8 June 2018

Report returned with comments: 21 June 2018

Final report issued: 28 June 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: 27 July 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 endeavoured 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.