Site visit audit report on compliance with HTA requirements

BUPA Cromwell Hospital

HTA licensing number 40011

Licensed for

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

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), 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

20 February 2018

Summary of Audit findings

BUPA Cromwell Hospital (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to documentation, incident reporting and licensing arrangements.

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, R**

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), retrieval of an organ (R)

Licensable activities carried out by the establishment – Transplant activities

Organ type	Kidney
Adult living	**OC, P, I**

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), implantation of an organ (I)

Background to the establishment and description of audit activities undertaken

BUPA Cromwell Hospital (the establishment) is a private hospital in London 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 currently retrieves

and implants kidneys from living donors. The directed living donations involve adult donors, with the majority of the patients coming from overseas, having been referred to the establishment by their respective embassy. There is no paediatric service.

The establishment currently does not perform living liver lobe transplants, but has plans to re-start this programme using staff from another HTA-licensed transplant centre. The living donor liver programme was not assessed during the audit but a discussion was held with both the Consultant Surgeon from the other licensed establishment and BUPA Cromwell Hospital staff regarding this activity (see *Advice*, item 4).

Living Kidney Donor Transplants

Potential donors and recipients are often related, have undergone some initial assessment in their home country and come to the hospital together. The establishment carries out its own donor characterisation, which includes repeating all mandatory tests prior to the transplant taking place. The Living Donor Co-ordinator (LDC) provides information to potential donors on the risks associated with living donation.

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 another hospital. The microbiological testing laboratory, which is located at the establishment, provides microbiology services to support transplant activities under a contract between the laboratory and the establishment.

The donor and recipient are initially seen by the Consultant Nephrologist, who takes a full medical history from each. The Nephrologist asks potential donors about their social and medical history. This information is recorded on a form which is kept in the patient notes (see *Advice*, item 1). 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. Once the IA completes the assessment, HTA approval is sought.

The Consultant Surgeon checks that consent for retrieval is in place before the procedure commences. Transplants take place in dedicated theatres within the hospital. The donor and recipient are in adjoining theatres and the Consultant Surgeon performs the retrieval and the transplant.

Stocks of perfusion fluids used during organ retrieval and transplant are kept in temperature-monitored fridges and brought into theatre on the day of the transplant. 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.

During the audit, certification relating to sterile services was reviewed. This confirmed that the cleaning and sterilisation procedures were valid and meet the required standards.

Both the internal and external testing laboratories undertaking donor and organ characterisation assessments are appropriately accredited by a relevant body. The audit team verified that the Department of Pathology, which includes virology testing and histopathology laboratories, has current Clinical Pathology Accreditation (CPA) certificates.

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.

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 and the embassy from which the referral was made. The centre provides considerable information to the donor regarding the importance of follow up appointments and annual checks.

Audit of clinical notes and document review

During the establishment's audit, a review of four sets of living kidney transplant recipient clinical notes and associated donor files was undertaken by the audit team.

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

- HTA-A and HTA-B forms
- Records of perfusion fluids/batch numbers used
- HTA approval form
- 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

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.	CT2	The establishment is advised to consider having social history questions for potential donors translated into the relevant language of the donor so that, if preferred, a potential donor could read and answer questions in private, without the need for a translator.
2.	S3	The contract with the microbiology testing laboratory should explicitly state that incidents need to be reported to the establishment within 24 hours of discovery.
3.	General advice	The establishment's SOP 'Human Tissue Authority Organ Transplantation' has a procedure which relates to packing an organ for transportation in the unlikely event that the organ cannot be implanted into the intended recipient and is redirected to the deceased donor organ pool. The SOP states that the organ should be packed in line with European Regulations and the EU Tissue and Cells Directive. The establishment is advised to amend the SOP removing the reference to the EU Tissue and Cells Directive as this in incorrect. In addition, on the advice of the audit team, the establishment has added the activity of transport to their licence in the unlikely event that an organ needs to be packed and re-directed to the deceased donor pool. This advice was acted on prior to this report being published.
4.	General advice	During the audit, the establishment was advised to contact the HTA before the start of the living liver donor transplant programme so that a review of the relevant procedures and associated documentation can be undertaken before any activity commences. A date has been arranged for the HTA to return to the establishment to review the relevant documentation prior to this report being published.

Concluding comments

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

- The establishment has created their own SOPs based on the national operating procedures that include flow charts which help to make the procedures clear for staff

to follow.

- The patient to staff ratio is low.

- The LDC has developed a patient education pack so that patients understand what to expect post transplantation such as post-operative medication regime and recognising post-operative complications.

The HTA has given advice to the establishment with respect to documentation, incidents and licensing arrangements.

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

Report sent for factual accuracy: 20 March 2018

Report returned with comments: 3 April 2018

Final report issued: 3 April 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.