Site visit audit report on compliance with HTA requirements

London Independent Hospital – BMI

HTA licensing number 40067

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 Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

17 November 2016

Summary of Audit findings

London Independent Hospital - BMI (the establishment) was found to have met all assessment criteria. The HTA has given advice to the establishment with respect to donor/organ characterisation, traceability and adverse event reporting.

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), 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 living	**OC, P, 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

The London Independent Hospital (the establishment) has been licensed since January 2013. The establishment carries out living donor kidney transplants.

The transplant service is surgeon led with input from relevant specialties such as nephrology. The establishment provides the service predominantly to private patients where both the donor and recipient have been referred through the embassy of their home country. Although only four transplants have been carried out since the establishment has been licensed, multiple potential donors and recipients have been screened by establishment staff but have been found to be unsuitable for transplant surgery.

Initially, following the referral of a potential donor and recipient pair, the transplant surgeon and the consultant nephrologist will review the medical information that has been provided by the referring centre. If there are no contraindications at this stage, the donor and recipient will be scheduled for face-face consultations with the surgeon and nephrologist. If both the donor and recipient are found to be suitable for the surgery, the donor work up will commence.

Donor work up is undertaken by the nephrologist and typically takes two weeks however, more complicated donor work up cases may require additional screening and tests, meaning that the work up time is extended. Where the potential donation and transplant is more complicated, the transplant team undertake a wider, multidisciplinary team approach involving additional medics who input into the donor and recipient assessment process. As part of the donor work up, donor and organ characterisation tests that have taken place in the donor's home country are repeated by the establishment. These tests include the mandatory serological screens and other mandatory organ and donor characterisation assessments. The establishment uses two laboratories to undertake donor characterisation tests. One of these laboratories is currently accredited under the Clinical Pathology Accreditation (CPA) system and the relevant certification was reviewed during the audit. The other laboratory has been assessed for ISO 15189 compliance; however, certification has not yet been granted although it was understood to be pending at the time of the audit. The existing CPA accreditation certificates for this laboratory were provided.

If the donor is clinically suitable, the transplant surgery is scheduled and the donor and recipient are interviewed by an Independent Assessor. Transplant surgery usually takes place on a Sunday which is a time when the establishment's demand for theatres is reduced meaning the surgery can take place in adjacent theatres. The surgeon, nephrologist and anaesthetist meet on the day prior to surgery to discuss the transplant and review the medical information relating to the donor and recipient.

The retrieving surgeon undertakes the retrieval surgery in the first theatre and following retrieval, perfuses it within the same theatre. The establishment does not maintain a stock of perfusion fluid due to the sporadic timing of the transplants. Instead, the required amount of perfusion fluid is purchased once the surgery has been planned and is stored in, and issued by, the establishment's pharmacy department when it is required for the transplant. As the retrieval surgery is ending, the recipient is brought in to the second theatre and is prepared for surgery. The retrieving surgeon also undertakes the implantation surgery and is assisted by a senior surgical team who are also qualified and capable of completing the transplant surgery in an emergency.

The surgeon completes the relevant traceability paperwork which includes details of the donor and recipient in addition to details relating to the surgery, surgical timings and perfusion fluids used. The paperwork is returned to NHSBT by the Director of Clinical Services.

Following surgery, the donor is reviewed by the surgeon and is seen again at discharge, again at ten days after surgery and finally at six weeks following the nephrectomy. Following these consultations, if there are no complications arising following surgery, the donor returns to their home country where they are discharged to a consultant at a transplant centre located there. The consultant in the donor's home country is sent relevant clinical details relating to the donor including a discharge summary and a copy of the operation notes. The

establishment's surgeon reported that he often receives further updates on the donor's progress as they continue to be followed up post donation, in their home country.

The establishment undertakes an annual review of the surgical staff's professional development and verifies their professional registration. Theatre nursing staff employed by the establishment have annual appraisals, checks on their professional registration, undergo competency assessments and undertake mandatory training.

The establishment has used procedures taken from the national operating procedures 001, 002, 004, 005 and 006 to produce a suite of standard operating procedures (SOPs) covering the transplant activity. In addition, any serious adverse events and reactions (SAEARs) would be reported to NHSBT as described in the NHSBT SAEARs reporting procedure however, at the time of the audit, there have been no such incidents.

During the audit, certification relating to the sterilisation service was reviewed and was found to be satisfactory. Also reviewed was the establishment's medical devices management policy which stipulates that medical devices purchased by the trust must be CE marked which indicates that they are compliant with the relevant legislative requirements governing medical devices.

A review of three sets of transplant records using donor and recipient clinical notes was undertaken during the audit. For all three transplants, the clinical notes contained evidence of: donor consent, routine blood tests and mandatory serological screens, copies of the HTA-A and HTA-B traceability forms which include details of the perfusion fluid used, the nephrologist's letter stating that based on their assessment the person is a suitable donor and evidence of the HTA's approval of the donation.

Compliance with HTA assessment criteria

All applicable HTA assessment criteria have been assessed as fully met.

Advice

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

No.	Assessment Criterion	Advice
1.	CT2 CT4	The majority of the donor and organ characterisation information was found within the donor's clinical records. However, evidence of all elements of the social history, such as questions regarding IV drug use, was not found during the audit of clinical records. The national operating procedure relating to donor characterisation states that records of characterisation assessments should be documented within the donor's clinical records. The nephrologist stated that the minimum data set for donor characterisation as defined in Appendix A, part A of the framework document, was always obtained and these questions asked during consultations with the donor. However, records of these consultations had not been clearly documented. The establishment is advised to consider preparing a check list that can be used when undertaking donor and organ characterisation. This checklist could be used by the clinician to record that they have reviewed the necessary donor and organ characterisation information and whether it is acceptable or not. In addition, as the majority of donors originate from the same country, the establishment may wish to consider translating some of the sensitive social history questions into the donor's own language. This would allow the donor

No.	Assessment Criterion	Advice
		to answer the questionnaire without using an interpreter which may help to support the donor's confidentiality.
2.	CT3	The establishment has a document detailing the serological donor characterisation tests that are undertaken and which laboratory is used for these tests. This testing document includes testing for Human T-cell lymphotropic virus (HTLV); however, following a review of donor clinical notes, it was apparent that HTLV testing is not performed. Donor/organ characterisation tests at the establishment are carried out under the direction of the medical staff. While the current testing undertaken by the establishment meets the requirments of the Quality and Safety of Organs Intended for Transplantation Regulations 2012, the establishment is advised to review current guidance from the relevant national bodies regarding donor testing. Donor testing guidance includes additional testing for living organ donors for example, HTLV and syphilis testing. Once this review of donor testing has been performed, the establishment should update the document detailing the donor tests that are performed so that the document accurately reflects the tests being carried out.
3.	TC1	The establishment is advised to update the SOP based upon the National Operating Procedure 006 to include details of the person responsible for returning HTA-A and HTA-B forms to NHSBT, namely, the Director of Clinical Services.
4.	TC2	During the audit, a review of clinical notes took place from both the donor and recipient. All of the required information was correctly filed however, there was no dedicated area within the notes to store key transplant related documents. The establishment may wish to consider adding a section to donor and recipient notes where key documentation relating to the transplant can be filed and therefore be immediately available for review by the clinical team.
5.	S2	The establishment's incident reporting procedure references an out of date NHSBT incident reporting SOP. The establishment is advised to update the procedure so that the latest version of the incident reporting SOP (3888/2) is referenced within the establishment's procedural documentation. In addition, the establishment's internal serious incident policy includes references to external organisations to which incidents must be reported. The establishment is advised to update this document so that it includes reporting organ donation and transplantation related incidents to NHSBT within 24 hours of their discovery.

Concluding comments

The surgeon and nephrologist work closely together during donor and recipient assessment and if required include other medical colleagues for more complicated cases. Clinical staff have immediate access to specialist staff at the diagnostic laboratory if needed. By undertaking the retrieval and transplant surgery on a Sunday the team have two theatres available to them. Since transplant surgery is the only surgical activity taking place on that day, the time between retrieval and implantation is minimised.

The HTA has given advice to the establishment with respect to donor/organ characterisation, traceability and adverse event reporting.

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

Report sent for factual accuracy: 15 December 2016

Report returned with comments: 22 December 2016

Final report issued: 19 January 2017

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.