Site visit audit report on compliance with HTA requirements

Imperial College Healthcare NHS Trust

HTA licensing number 40044

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 Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

17- 18 October 2017

Summary of Audit findings

Imperial College Healthcare NHS Trust (the establishment) was found to have met all assessment criteria.

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

Particular examples of strengths and good practice are included in the concluding comments section of the report.

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	Pancreas
Adult living	**OC, P, T, I**	
Adult deceased	**OC, P, T, I**	**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

Imperial College Healthcare NHS Trust (the establishment) has been licensed since December 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. Licensable activities are undertaken at the Hammersmith Hospital.

The Imperial College Renal & Transplant Centre, based at Hammersmith Hospital, provides adult kidney and pancreas transplantation services for the large population served by the unit covering North-West London as well as referrals from the Lister Hospital in Stevenage, Hertfordshire. Transplant surgeons and nephrologists from the establishment attend clinics at the Lister Hospital to assess patients referred for transplantation. The establishment undertakes transplants of kidneys from living and deceased donors as well as pancreas and simultaneous pancreas and kidney transplants from deceased donors. In 2015 to 2016 the establishment transplanted 36 kidneys from living donors and 121 kidneys and 12 simultaneous pancreas and kidney transplants from deceased donors. Surgery takes place in a dedicated theatre or in an emergency theatre if needed.

Perfusion fluids used are stored in a fridge within the theatre suite. Theatre staff are responsible for monitoring the temperature of the fridge and ensuring that the perfusion fluids are in-date (see advice and guidance, item 2). Additional stocks of perfusion fluid are stored in a cupboard within the perimeter of the theatres. The temperature of this stock cupboard is not monitored. The establishment, on occasion, uses a hypothermic perfusion device to perfuse kidneys. This is when more than one organ has been offered to the establishment, or if the patient receives a pancreas and kidney transplant, as the pancreas is transplanted before the kidney.

Living Donor Kidney Transplants

Patients attending dialysis units and low clearance clinics will be given information about the different transplant options. In addition, three to four times a year the establishment runs larger transplant information events. The living transplant coordinator will provide potential donors with information about living donation and a health screening questionnaire. The questionnaire covers past medical and social history. Both potential donor and recipient are invited for a consultation with the living transplant coordinator. During this visit an assessment of the donor recipient interaction is made and the potential donor will have bloods and a medical history taken. If the potential donor is a good cross match then they are invited for further medical investigations. The donor is then seen by a consultant nephrologist and consultant surgeon. The establishment makes every effort to ensure that the donor and recipient are seen by different medical staff. The living transplant coordinator uses a ‘living donor characterisation’ form which includes details of the tests performed and prompts relating to the various discussions to be held with the donor including independent assessor checks and HTA approval. Living donors are then discussed at multidisciplinary team (MDT) meetings which include the establishment’s surgical staff, nephrologists, anaesthetist, and HLA lab representative.

The recipient is admitted on the day before surgery and the donor on the day of surgery. The Specialist Registrar (SpR) will clerk and re-consent both patients. The recipient is not brought to theatre until the retrieval is complete and the retrieval surgeon has checked on the status of the donor. The establishment will try to ensure a different surgeon undertakes the kidney transplant. If the donation is part of the paired and pooled scheme then the living transplant coordinator will have liaised with NHS Blood and Transplant (NHSBT) beforehand to discuss arrangements between retrieval and transplant centres. This will include pre-booking of the NHSBT contracted courier. Contact will be made with the surgeons to check if all centres are ready and there are no issues. The living transplant coordinator is present in theatre. Photographs of the kidney are taken and the retrieving surgeon will pack the organ and complete the paperwork including the HTA A form. The establishment has adopted NOP003

which gives details on how to pack organs for transport. The living donor coordinator checks that everything is complete and takes the kidney to the De Wardener ward in the renal centre to await the NHSBT courier.

Live kidney donors are seen daily by the retrieving surgeon after surgery. The surgeon then reviews the donor at two weeks and six weeks post-surgery. The donor is then seen at the establishment's live donor clinic at three, six and twelvemonths post-surgery. Following these assessment visits the donor then is reviewed annually in the establishment's live donor clinic.

The establishment will consider donors from overseas but will give careful consideration whether they will be able to provide some medical screening information prior to travelling to the establishment and also have access to medical follow up post organ donation.

Deceased Donor Kidney and Pancreas Transplants

The NHSBT Duty Office telephones the on-duty SpR when an organ becomes available for one of the establishment's recipients. The SpR will review the information on the electronic offering system (EOS) and assess the donor and organ characterisation information against the identified recipient or patients on the waiting list where applicable. If the organ is suitable for the recipient the SpR will contact the Consultant Nephrologist to discuss further then call the transplant surgeon to discuss the case. The SpR will then contact the Duty Office to accept or decline the organ. The transplant surgeon would have previously discussed with the recipient the type of organ that may become available and the various risks and benefits in receiving, for example, an extended criteria organ. If any information is outstanding on EOS the transplant will not proceed until this is known. The SpR relies on the Duty Office to alert the establishment to any updates on EOS.

Recipients on the waiting list for an organ are tissue typed by the Histocompatibility and Immunogenetics (H&I) laboratory every three months. The SpR will contact the H&I laboratory to see if there is a virtual cross match or if a wet cross match is required. If a cross match is required a request for peripheral blood will be made via the Duty Office and this is dispatched in advance of the organ.

The recipient is contacted about the organ offer and asked about any sensitising events they may have experienced, such as blood transfusions. On admission, the recipient is clerked by the Renal Registrar and Surgical Fellow. Bloods are taken for an up to date set of test results and the patient consented for the procedure.

The NHSBT courier delivers the organ(s) to the De Wardener ward where the ward manager or a band six nurse will accept and sign for the organ. The organ box is taken to the treatment room where two nurses will check the contents and complete an organ checklist and ensure that there is sufficient ice. If ice has to be topped up this is also recorded on the organ checklist. However, with the new NHSBT transport boxes the establishment reported that this is rarely required. If more than one organ is received at the same time, a label with the name of the recipient is affixed to the outside of each transport box. If the organ is received during the day, staff from the H&I laboratory will be informed and will collect the blood, spleen and lymph immediately. Otherwise these are placed in a fridge located in the drug room (see advice and guidance, item 1).

The Transplant surgical fellow goes to the De Wardener ward and cross checks with the nurse in charge to ensure that the correct organ is collected. The organ is taken to theatre for back-bench preparation. A sample of the perfusion fluid is taken and sent for microbiology testing. During the transplant all records including batches of perfusion fluid used are recorded on a white board in theatre. At the end of the procedure this information is recorded into the patient notes. The Transplant surgeon also completes the HTA B form. Most of the patient records are available electronically, however, some information continues to be in

paper form and these records are stored in the in the ward manager's office on De Wardener ward (see advice and guidance, item 3).

Completed HTA A and HTA B forms are checked by a senior nurse on the De Wardener ward, the form is then scanned and emailed to the establishment's data information team who in turn send the scanned form to NHSBT. Alternatively the senior nurse may scan and send the form directly to NHSBT. In either case, a spreadsheet confirming that the forms were sent to NHSBT is then completed.

The audit consisted of a visual tour that followed the pathway of the organ from receipt through to the implanting theatre and the donor testing laboratories.

Donor Testing

The audit included a visit to the testing laboratories undertaking donor and organ characterisation assessments. Tissue typing, virtual and wet cross matching takes place at the H&I laboratory which is based alongside the Pathology laboratory at Hammersmith Hospital. The Cellular Pathology laboratory, based at Charing Cross Hospital, undertake tests for HIV 1/2, HBV, HCV, HTLV 1/2, CMV, EBV, syphilis and *Toxoplasma* for living donors. A sample of transport fluid which surrounds kidneys from deceased donors is sent to the microbiology laboratory for analysis. Results are communicated to the transplant surgeon who in turn will inform NHSBT Duty Office if any microorganism is detected in the transport fluid as it may have implications for recipients of other organs from the same deceased donor. All laboratories are accredited by Clinical Pathology Accreditation (CPA) or United Kingdom Accreditation Service (UKAS). In addition, the H&I laboratory is accredited by the European Federation of Immunogenetics (EFI).

Document Review

The electronic clinical notes relating to two living donor/recipient kidney transplants and two deceased donor kidney transplants were reviewed. Records of consent, mandatory test results, details of perfusion fluids used, core donor data forms and donor assessments were reviewed. The paper copies of the associated HTA A and HTA B forms and the living donor checklist were also reviewed. No anomalies were found. Additional documents relating to the Trust's procedure for the procurement of only CE marked devices, the audit of the sterile services and Serious adverse event and serious adverse reactions (SAEARS) policy (see advice and guidance, item 4) were also seen.

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:

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

No.	Assessment Criterion	Advice
1.	P1	The temperature of the fridge used to store the deceased donor blood sample, lymph and spleen is not monitored. In addition the temperature of the fridge used to store perfusion fluids is not always recorded. The establishment is advised to consider using a maximum/minimum thermometer to record the storage fridge's temperature which could be reviewed daily and prior to any perfusion fluid being removed from storage. This would allow any temperature deviations to be detected, even if the operating temperature of the fridge has returned to normal following a deviation out of hours.
2.	P3	The fridge used to store perfusion fluid has an alarm that rings locally in theatre. During the visual audit it was noted that the alarm was switched off. The establishment is advised to put systems in place to ensure that the alarm is not switched off and to test the alarm to assure itself that the alarm is operational and that theatre staff know who to contact in the event the alarm is triggered.
3.	CT6	The establishment has the majority of donor/recipient records stored electronically. However, some records are still in paper format and are not held centrally but on the transplant ward. The establishment is advised to explore whether all records could be maintained in electronic format. The establishment is also advised to review the WHO check list so that information such as confirmation that EOS was reviewed by the transplant surgeon can be confirmed / recorded, and that for live donors HTA approval has been granted.
4.	S1	The establishment has a SAEARS reporting policy. However, this makes reference to the NHSBT operating procedure 3888/1 which has now been superseded by 3888/2. The establishment is advised to review this new document and to update its SAEARS reporting policy accordingly.

Concluding comments

A number of good practices were observed during the audit. The establishment will adjust the technique of live donor nephrectomy procedure according to the type of donor. There is a close working relationship with the H&I laboratory including their participation in MDT meetings. The establishment recognises the need to review and improve their practices. This has resulted in the recruitment of a recipient transplant coordinator.

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

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

Report sent for factual accuracy: 14 November 2017

Report returned with comments: 18 December 2017

Final report issued: 20 December 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.