Site visit audit report on compliance with HTA requirements

King's College Hospital NHS Foundation Trust

HTA licensing number 40023

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

15 and 16 November 2017

Summary of Audit findings

King's College Hospital NHS Foundation Trust (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to documentation, audit of records, agreements with third parties, temperature monitoring and follow up of living donors.

Particular examples of 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	Liver	Kidney	Pancreas	Small bowel/ Multivisceral/ Modified Multivisceral
Adult living	**DC, OC, P, T, R**	**-**		**-**
Adult deceased	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**	**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	Liver	Small bowel/ Multivisceral/ Modified Multivisceral	Kidney
Adult	**OC, P, T, I**	**-**	**OC, P, T, I**
Paediatric	**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

King's College Hospital NHS Foundation Trust (the establishment) has been licensed by the HTA 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. The establishment undertakes adult liver, paediatric liver, adult small bowel/multivisceral transplants and paediatric small bowel/multivisceral transplants of cadaveric donor organs. The establishment also has a living donor liver transplant program through which living adult donors may donate part of their liver to adult or paediatric recipients. The establishment additionally participates in National Organ Retrieval Service (NORS) through which it retrieves abdominal organs from deceased donors including liver, kidney and pancreas.

The establishment is based at King's College Hospital, London. Transplants at the establishment take place in a dedicated liver transplant theatre and in addition, two hepatobilary theatres within the hospital. Stocks of perfusion fluids used during organ retrieval and transplant are kept in temperature-monitored fridges adjacent to the hepatobilary theatres. If the fridge's temperature deviates from the expected range, an alarm is triggered and an automated call is made to the on-call member of staff in theatres. In addition to storing fluids in this area, equipment used by the organ retrieval team is also stored. Consumable items of equipment used during organ retrieval and transplant are held within a temperature controlled central storage system which automatically requests replacement stock as items are removed from the store.

Retrieval equipment and organ transport boxes are also held in the establishment's theatre area. Retrieval kits have 'kit-lists' so that staff replenishing items following a retrieval and preparing the kit for another retrieval have a guide on items that should be included in the kits. The establishment uses organ transport boxes provided by NHSBT for the transport of kidneys and pancreases retrieved during abdominal organ retrievals. The establishment sources its own transport boxes used for transporting livers and multivisceral organs.

Equipment used during organ retrievals and transplants is CE marked and meets the requirements of the medical devices regulations. The establishment has a standard operating procedure (Management and Procurement of Medical Devices – SOP4) which mandates that all equipment that is purchased must be compliant with the medical devices regulation's requirements. In addition, the establishment's Trust's medical devices policy states that clinical staff are responsible for ensuring that only medical devices that are CE marked as such can be purchased and used. Cleaning and sterilisation of reusable equipment is undertaken by the Trust's sterile services provider. Certification relating to the sterile services demonstrating that the cleaning and sterilisation procedures meet the required standards was reviewed during the audit. The establishment's SOP4 details the requirement for cleaning and sterilisation services to meet the required standard.

Although not taking place at the time of the audit, the establishment has been involved in various clinical trials during which organs are mechanically perfused prior to their implantation. Establishment staff informed the audit team that equipment used in these trials is CE marked for the specific purpose that they are being used for and therefore meet the requirements of the medical devices regulations. As it is likely that the establishment will be involved in further clinical trials involving mechanical perfusion, advice was given during the audit about ensuring that any organ characterisation data that may be obtained during the mechanical perfusion of organs must be retained for the required 30 year period (see advice item 1).

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 medical microbiology laboratory, which includes virology testing and histopathology laboratories, have current Clinical Pathology Accreditation (CPA) certificates. The establishment's medical microbiology laboratory has also been visited by the UK Accreditation Service (UKAS) and compliance information towards the accreditation under the ISO:15189 accreditation scheme has been submitted. The external histocompatibility and immunogenetics laboratory has CPA accreditation and is additionally accredited by the European Federation of Immunogenetics (EFI).

Medical activities being undertaken at the establishment are performed under the advice and guidance of a registered medical practitioner (RMP). The establishment's SOP5 details the staff undertaking various medical activities and which activities are overseen by which RMP. Nursing staff undergo an induction into transplant methodologies and have comprehensive training and competency records detailing their training and sign off. Surgical staff train in transplant activities and are supervised by mentors before being signed off as competent to work unsupervised by senior surgical fellows. All staff at the establishment undergo twelve monthly appraisals.

Cadaveric Donor Liver Transplantation

Organ offers from NHSBT, the national organisation responsible for organ allocation, are received by a transplant coordinator (the coordinator) one of whom is on-call 24 hours a day. Donor identifiers are used by the coordinator to access the Electronic Offering System (EOS) database which contains donor and organ characterisation information. The coordinator then completes an in-house designed 'Donor Offer Form' with key details about the donor and organ characterisation. If the donor is aged 40 or under the establishment, in accordance with national guidance, considers splitting the donor liver so that it can be used in two transplants, one paediatric and one adult. Should this be the case the coordinator will contact a consultant paediatric recipient transplant surgeon, otherwise, the coordinator contacts an adult recipient transplant surgeon so that they may review the donor and organ characterisation information. While reviewing the characterisation information and throughout the transplant pathway, the transplant surgeon will liaise with other medical colleagues and specialties as necessary, for example, hepatologists or nephrologists. The implanting surgeon will also review all relevant characterisation information via EOS prior to implantation.

If the donor organ offer is accepted, the coordinator liaises with the NHSBT Hub, specialist nurse for organ donation (SNOD) at the donor hospital, theatres and intensive care at the establishment to start planning the retrieval and transplant surgery and associated timings. The retreiving surgeon may speak directly to the implanting surgeon as necessary to give information directly about the donor or organ characterisation. All conversations and requests for information are recorded in a contemporaneous record maintained by the coordinator. If required, additional tests may be requested such as histological analysis of any suspicious lesions. If the establishment's own retrieval team is retrieving the organ, histology samples may be brought back to the establishment for analysis, alternatively, analysis may take place locally at the retrieval centre or at another recipient centre. Where additional assessments occur at the establishment, results of the analysis are sent to NHSBT's Hub so that they can be shared with other recipient centres.

If any of the donor or organ characterisation information or additional tests undertaken on the donor or organ indicate that there may be increased risks associated with the organ, the implanting surgeon will discuss these risks with the recipient prior to surgery; the surgeon discusses any risks and benefits of proceeding with the transplant so that the recipient is fully informed. Details of these risk benefit discussions are recorded in the recipient's clinical notes and a record that they have occurred is kept within the contemporaneous record made by the coordinator on the Donor Offer form.

The time that the organ is received at the establishment is recorded on a dedicated form, the Organ Safety Checklist. The establishment undertakes and records each of a three stage check on the organ with each check being recorded and countersigned on the Organ Safety Checklist. Initially, the paperwork accompanying the organ is checked to verify that the details arriving with the organ match the details that the establishment were expecting such as donor identification numbers and donor blood group.

The integrity of the organ and its packaging are checked in theatre when the transport box is opened and the organ removed for pre-implantation preparation by a surgeon. Samples of perfusion fluid surrounding the organ are sent for microbial analysis. In addition to checking the organ itself, the integrity of the transport box and amount of ice in the transport box are also checked to ensure that the integrity of the organ has been maintained during transport to the establishment.

Finally, the implanting consultant surgeon verifies the donor details and the condition of the organ prior to implantation. This third check that is recorded on the organ safetly checklist also records that having reviewed the organ itself, the accompanying paper work and the donor and organ characterisation information that the implanting surgeon has assessed the organ as suitable and is willing to proceed with implantation.

Following the implantation of organs the surgeon completes the HTA-B traceability form which is returned to NHSBT by designated theatre staff.

The establishment may implant deceased donor kidneys during combined liver and kidney transplants. Should this occur the same transplant pathway as described above is followed with additional support from relevant renal specialties. In addition, an implanting renal surgeon from another HTA licensed establishment attends the transplant surgery to perform the implantation procedure.

Living Donor Liver Transplantation

All living liver donors refer themselves to the establishment. A living liver donor coordinator (the LD coordinator) provides the potential donor with written information about living donation and takes a broad medical history including the potential donor's age, weight, medical and surgical history. The potential donor is discussed with a consultant surgeon who reviews the broad history to determine if any factors may rule out the potential donor.

If suitable for donation, the potential donor commences the donor suitability assessments with the hepatologist and surgeon. A more detailed medical history is taken and the potential donor is given more detailed information about being a live liver donor through an education session. Blood tests are undertaken and a liver ultrasound performed. The ultrasound is reviewed by a surgeon and again, if suitable, the potential donor will undergo further assessments including computed tomography and magnetic resonance imaging. The hepatologist decides if any further investigations are required such as cardiological or respiratory assessments. At this stage, potential donors are reviewed again by the hepatologist, psychiatrist and anaesthetist. Once the characterisation assesments have been undertaken, an interview with an independent assessor is arranged.

Following the review by the hepatologist and the surgeon, the potential donor is presented at a multidisciplinary meeting where it is decided if any further final assessments are necessary and if the potential donor is suitable to donate or not. Provided the HTA have authorised the living donation and the donor is suitable, transplant surgery will be arranged with the retrieval and implantation procedures overlapping in order to help minimise the cold ischaemic time.

Living donors are followed up by the surgeon post procedure, after discharge at one week, one month and three months post procedure. Living donors are then invited back to the establishment for life-long annual follow up.

Small Bowel/Multivisceral Cadaveric Donor Transplants

The establishment undertakes intestinal transplants into paediatric recipients. These can be isolated small bowel or liver and small bowel. Multivisceral transplants where stomach, liver and small bowel are transplanted are also undertaken as are modified multivisceral where stomach and small bowel are transplanted.

Potential recipients are referred into the establishment for assessment. Criteria such as the recipient having irreversible intestinal failure must be met before intestinal transplantation is considered. During the recipient's assessment, the clinical nurse specialist coordinates the assessments to be undertaken and gives information about the transplant process and life after intestinal transplant. Assessments include tests on heart, lungs and kidneys. The potential recipient is presented at a multidisciplinary meeting to investigate if they are suitable for transplant or if other, non transplant treatments may be more suitable. If suitable, the recipient will be registered with NHSBT and added to the transplant waiting list held by establishment.

Once listed the recipient is contacted regularly by the clinical nurse specialist who reviews their condition and finds out if the recipient's condition is stable or has changed. Transplant offers are received by the coordinators who are authorised to decline offers based on donor weight. If the donor's weight is too large the organs would not be suitable for transplant due to size mismatch between the donor and recipient. If the donor's weight is suitable, donor and organ characterisation data is downloaded from EOS by the coordinator, recorded on a donor referral form so that it may be shared with the implanting surgeon and medical staff to determine if they are suitable.

If accepted the role of the coordinator is very similar as for the cadaveric donor liver transplant pathway described above. Intestinal transplant organs are not retrieved by the NORS team and instead, the establishment always procures the organs itself. The recipient's transplant surgery takes eight to ten hours and is started once the retrieving surgeon has completed the retrieval and has inspected the organs. At this stage the retrieving surgical team and implanting team liaise with each other so that the implanting surgeon can assure themselves that the organs are suitable for implantation.

Following surgery, the implanting surgeon completes the HTA-B form which is returned to NHSBT by dedicated theatre staff.

Deceased Organ Retrieval

Once alerted to a potential donor by NHSBT's Hub, the establishment's transplant coordinators , inform the consultant surgeon about the donor and mobilise the NORS team members. The coordinator prints off the donor's details from EOS which are given to the retrieving surgeon and donor technician who also receive the timing details for the retrieval. The coordinator also arranges transport for the retrieval team. The donor technician collects and checks the retrieval kits with the scrub nurse.

On arrival at the donor hospital the retrieval team meet with the SNOD. The surgeon verifies the patient details during a briefing with the SNOD which includes reviewing a full medical history that is available for the donor, the donor's clinical notes, the consent documentation, brain stem death tests if applicable, blood group, virology testing results and other blood tests.

Prior to the retrieval procedure starting, the retrieval team has a team briefing which includes other retrieval teams present such as the cardiothoracic team. A further checklist held by the SNOD is also undertaken prior to retrieval commencing. During retrieval, the lead surgeon may also liaise with implanting surgeons at transplant centres if requested to do so.

The surgeon retrieves the organs and checks their anatomy. The scrub nurse assists in the packing of the liver and kidneys. If anything unusual is identified during retrieval, for example, a suspicious nodule on a kidney, the retrieving surgeon will liaise with the coordinator at the establishment who will arrange for histopathology and recipient centres to inform the implanting surgeons.

Upon return to the establishment the retrieval kits are re-stocked so that they are ready for use should another retrieval be requested.

Audit of Clinical Notes

During the establishment's audit, a review of recipient clinical notes and associated donor files was undertaken by the audit team as described below:-

- Two sets of notes relating to deceased donor liver transplants (1 x adult, 1 x paediatric)
- One set of notes relating to deceased donor small bowel transplant (paediatric)
- Three sets of notes relating to living liver donors and the respective recipients (1 x adult, 2 x paediatric)

In all of these cases, where applicable, the following records were reviewed: HTA-A and HTA-B forms, copies of EOS information, the donor referral record, virology results, donor blood group form, recipient consent and the organ safety checklist.

One minor anomaly was identified during the audit. In one set of living donor liver transplant notes, details of the perfusion fluids used during retrieval had not been recorded on the HTA-A form as required by the regulations (see advice item 3).

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.	CT4	The establishment has used mechanical perfusion equipment in the past and may do so in the future. During the mechanical perfusion of the organ any data that is used for organ characterisation, either from the perfusion machine itself or from testing being performed while the organ is being perfused, must be stored for the required 30 year period. The establishment is advised to consider if such characterisation data has been/will be generated during mechanical perfusion of organs and to develop systems to ensure that any such characterisation data is maintained for 30 years as required by the regulations.
2.	R4	The establishment follows up living donors immediately post surgery, at one week post surgery, at one and three months post surgery before annual follow up at the living donor clinic. Living donors are discharged into the care of their GP in addition to their annual follow-up at the establishment, or annual follow up at their local hospital. Upon discharge of a living donor, a letter is sent to the donor's GP. The establishment is advised to consider amending the content of this discharge letter to include a reminder to the GP that should the living donor present with any medical conditions which may have an impact for the organ recipient, that the establishment should be contacted immediately so that the recipient can be reviewed and followed up as necessary. This may facilitate earlier detection of medical conditions that could impact an organ recipient. This is of particular importance in cases of non-directed altruistic living donations where there is no link between a donor and the recipient.
3.	P3	During the audit of transplant records, an anomaly was identified. In one set of living donor liver transplant notes, details of the perfusion fluids used during retrieval had not been recorded on the HTA-A form as required by the regulations. The establishment is advised to periodically audit a sample of the HTA-A and HTA-B forms to verify that they have been fully and correctly completed. *Following the site visit audit, the establishment informed the HTA that formal audits, in addition to the current post comepletion checks, will be undertaken at the establishment.*
4.	TP3	The establishment has created a detailed SOP covering the packing of organs prior to transplant. The establishment has appended new colour coded labels issued by NHSBT to label organ transport boxes for kidneys, pancreases and hearts being sent for valve procurement, to the SOP. The establishment is advised to amend SOP003 relating to the packing of organs so that details of the coloured labels and coloured bag ties used when

No.	Assessment Criterion	Advice
		packing the above organs are included in the SOP's text.
5.	TP5	The establishment has a close working relationship with the transport provider which provides transport for both unaccompanied organs and the establishment's retrieval team. There is also a dedicated point of contact at the provider who deals specifically with the establishment. The establishment has copies of the transport provider's driver's manual which included a statement that all adverse events and incidents must be reported to the establishment by the drivers. Following an update to the driver's manual however, the text placing a duty to report all adverse events and incidents to the establishment has been removed. The establishment is advised to liaise with their contact at the transport provider to have the instruction to report adverse events and incidents to the establishment added back into the new version of the driver's manual. In addition, there is no documented agreement between the transport provider and the establishment. The establishment is also advised to work with the contact at the transport provider to document a set of service provision criteria which should include the necessity to report all adverse incidents and events to the establishment should they occur.
6.	General	The establishment maintains a stock of fluids used during retrieval and transplant in temperature monitored fridges so that it is maintained at the correct temperature to use. A bulk supply of fluids and other consumables is also kept in a store room within the theatre complex, however this store room is not temperature monitored. The establishment informed the audit team that there are plans to add temperature monitoring to the store room. The establishment is advised to continue with their plans to monitor the temperature of the store room so that it may assure itself that stock is being maintained at the correct temperature.

Concluding comments

Areas of good practice were observed during the audit, some examples of these are included below.

- The establishment has used the national operating procedures as the basis for its SOPs. The SOPs have benefitted from reformatting making them easy to read so that they accurately reflect how the establishment undertakes its activity. These detailed SOPs are also helpful for new staff to train against.

- The training package for theatre staff is very detailed and helps in bringing new team members up to speed with both donor/recipient anatomy and terminology used during transplantation.

- The system of checking the organ three times prior to implantation and involving different staff including coordinators, theatre staff and implanting surgeon helps to assure the establishment that all relevant information and condition of the organ are verified prior to implantation. In addition, these checks are recorded on the Organ Safety Checklist and signed by the person conducting them. During the audit,

evidence of these checks taking place were seen during the review of clinical notes.

The HTA has given advice to the establishment with respect to documentation, audit of records, agreements with third parties, temperature monitoring and follow up of living donors.

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

Report sent for factual accuracy: 14 December 2017

Report returned with comments: 4 January 2018

Final report issued: 23 January 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.