Site visit audit report on compliance with HTA requirements

King's College Hospital NHS Foundation Trust

HTA licensing number 40023

Licensed for

- **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)**

- **Transplantation Activities: 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

18 September 2013

Summary of Audit findings

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

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	Liver	Kidney	Small bowel
Adult living	**DC, OC, P, T, R**	**-**	**-**
Adult deceased	**P, T, R**	**P, T, R**	**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
Adult	**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') is a liver transplantation centre. The majority of transplantation activity involves livers procured from deceased donors with, additionally, between 15-25 living liver lobe transplants performed each year. The establishment also performs up to five small bowel transplants for paediatric recipients each year.

Splitting of a liver from a deceased donor is usually performed once the organ has been received by the establishment. Both lobes may be implanted into recipients at the establishment; alternatively, the left lobe only will be implanted into a paediatric recipient with the right lobe being sent to another establishment for implantation. *In situ* splitting of a liver (i.e. within the donor's abdomen) at the donor hospital is rare.

The establishment provides staff to the National Organ Retrieval Service (NORS) for abdominal organ retrieval. In addition to UK retrievals the NORS team may, in a small number of cases each year, travel to mainland Europe to retrieve abdominal organs.

Surgeons from Guy's and St Thomas' NHS Foundation Trust (HTA licensing number 40029) can attend the establishment to implant a deceased donor kidney or pancreas during liver-kidney or liver-pancreas dual implant procedures.

Donor virology testing, histopathology and, for deceased donors, retrospective tissue typing are performed at the Trust's laboratories.

An action plan was issued to the establishment with its continuous licence in December 2012 in relation to assessment criteria TP3, TC1 and TP5. Meeting the shortfall against criterion TP3 was reliant upon the national roll-out of new organ boxes by NHSBT, a factor outside of the direct control of the establishment. As this roll-out had not taken place at the time of the audit, the HTA closed this shortfall on the action plan. Measures implemented in relation to assessment criteria TC1 and TP5 were described in the action plan, and were further verified at the audit.

The auditors traced the pathway followed by a liver received into the establishment, reviewed documentation, audited a selection of transplant records and had round-table discussions with staff involved in transplantation. The establishment has adopted, and adapted to suit local arrangements, all of the NHS Blood and Transplant (NHSBT) National Operating Procedures (NOPs).

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
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.	The establishment is not responsible for obtaining information relating to a deceased donor. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This is applicable for living donors. This criterion is fully met. Donor and organ characterisation information specified in Part A of the Annex to the Directive, which are set out in the HTA's 'Documentary framework for the quality and safety of organs intended for transplantation', is collected during donor work-up. Medical and behavioural information is recorded on the 'Living liver donor medical history' form.	**None**
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.	This criterion is fully met. Information specified in Part B of the Annex of the Directive, which are set out in the HTA's 'Documentary framework for the quality and safety of organs intended for transplantation', is routinely collected for both living and deceased donors.	**None**
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.	This criterion is fully met. This requirement is described in the establishment's operating procedure KCH.HTA.SOP.006 'Transfer and storage of donor and organ characterisation information and storage of traceability data'.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The establishment's laboratories have full CPA accreditation. Guy's and St Thomas' NHS Foundation Trust tissue typing laboratory has full CPA accreditation.	**None**

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.	This criterion is fully met. A transplant coordinator receives initial notification from a SN-OD of the offer of a deceased donor liver. The transplant coordinator transcribes core donor information from NHSBT's Electronic Offering System (EOS) onto a 'Donor referral form', and relays this information to a consultant surgeon, who may accept the offer based on the available details, or request additional information or investigations at the donor hospital. The NORS team will then be mobilised. During the retrieval, a member of the NORS team (the donor technician) provides verbal progress updates to the establishment. Medical and behavioural information about living donors is recorded on the 'Living liver donor medical history' form. Living donors undergo thorough psychiatric evaluation prior to donation. At living donor retrievals, a living donor coordinator relays information between the retrieving and implanting teams. These processes are described in the operating procedure KCH.HTA.SOP.001 'Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation'.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
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.	This criterion is fully met. For living donors, consent for procurement of a liver lobe is sought by a consultant surgeon, who explains to them the risks of the procedure, and the relative risks of donating either a left or a right liver lobe. The donor's consent for the fate of the liver lobe if, for whatever reason, it cannot be transplanted into the intended recipient, is also sought. For deceased UK donors, consent is sought by a SN-OD under NHSBT's licence. The consent form is reviewed by the NORS team as part of the pre-operative checklist.	**None**

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.	This criterion is fully met. This requirement is described in operating procedure KCH.HTA.SOP.004 'Management of procurement material and equipment in deceased and living donation and transplantation'.	**None**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. Certificates of Registration for the Sterile Services Unit, confirming its ISO9001 and ISO13485 accreditation, were seen at the audit.	**None**
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.	This criterion is fully met. Living donors have follow-up appointments at the hospital at three weeks, six weeks, three months and six months following discharge. They will have annual appointments thereafter, either at their local hospital or a medical practitioner. The 'Patient's guide to living liver donation' advises that a transplant coordinator should be contacted if the patient experiences any difficulty or complication related to the surgery.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
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.	This criterion is fully met. *Refer to assessment criterion R2.*	**None**
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. *Refer to assessment criterion R3.*	**None**

P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. Details of perfusion fluids used are recorded on HTA A and B forms. A sample of records for transplant procedures was audited. Perfusion fluid batch numbers and expiry dates were recorded by the establishment on the HTA A and B forms in each case.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
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.	This criterion is fully met. Livers are usually transported in proprietary cool boxes that are sealed with tape and with Clingfilm. 'Handle with care', 'organ in transit' and the establishment's address are written on the liver boxes in marker pen. The establishment is currently printing embossed labels bearing this information for the boxes. As part of a national trial, a deceased donor's liver retrieved by the establishment's NORS team may be transported from the donor hospital to the establishment in a Normothermic perfusion machine, instead of in a standard transport box. This will take place only if the donor's family, and the recipient, have given their agreement to this. In such cases, staff from the perfusion machine company will attend the retrieval, place the liver into the machine, travel with the NORS team to the establishment and remove the organ from the machine for implantation. The HTA A form always accompanies the organ to the implanting centre. Transport for the NORS team is carried out by a specialist courier company, which has provided this service to the establishment for several years. Transportation procedures and individual staff responsibilities at deceased donor retrievals are set out in KCH.HTA.SOP.003 'Packaging, labelling and transport of organs in deceased and living donation and transplantation' and in KCH.HTA.SOP.005 **'**Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation'.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. *Refer to assessment criterion TP1.*	**None**

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.	This criterion is fully met. *Refer to assessment criterion TP1.*	**None**
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.	This criterion is fully met. *Refer to assessment criterion TP1.*	**None**
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.	This criterion is fully met. Transportation of organs retrieved by the NORS team is carried out by a specialist courier company. A transplant coordinator will be informed immediately of any delay or other cause for concern during transport.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
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.	This criterion is fully met. Donor information is verified at three stages - when the organ is received, before back-benching and again before the organ is implanted. Each verification step is performed by two persons, one of whom is always a consultant surgeon, and this is recorded on the 'Organ safety checklist'. The surgeon's responsibility for verifying the donor identity, and completing the 'Organ safety checklist' and 'Surgical safety checklist', are documented in KCH.HTA.SOP.001 'Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation'.	**None**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion is fully met. Verification of the conditions of preservation and transport of an organ are recorded on the 'Organ safety checklist'. There is an 'additional comments' section on the form where any anomalies could be recorded.	**None**

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.	This criterion is fully met. If any of the information specified in Annex A of the Directive was unavailable, then a risk-benefit analysis would be documented in the recipient's operation notes.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
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.	This criterion is fully met. This requirement is described in KCH.HTA.SOP.001 'Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation' and in KCH.HTA.SOP.006 'Transfer and storage of donor and organ characterisation information and storage of traceability data'. Named transplant unit personnel return HTA A and B forms to NHSBT.	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. Deceased donors are identifiable by the NHSBT donor number, which can be found on EOS and the HTA A form. Recipients and living donors are identifiable by their full name, patient number and date of birth.	**None**
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.	This criterion is fully met. The date and time of arrival of an organ are recorded on the 'Organ safety checklist'. Collection by a courier of an organ to be delivered to another centre is recorded on the 'Transport handover form'. Operating procedure KCH.HTA.SOP.006 'Transfer and storage of donor and organ characterisation information and storage of traceability data' states that records of transportation will be stored by the hospital for thirty years after donation.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Serious adverse events and 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.	This criterion is fully met. There is a Trust 'Policy for the management, reporting and investigation of adverse incidents (including serious incidents)'. Incidents are reported internally through an online reporting system and are discussed at departmental and Trust level meetings The establishment has a documented procedure for reporting a serious adverse event or adverse reaction (SAEAR) to NHSBT. A named member of staff would make such a notification. Staff are aware of the requirement, and process, for reporting a SAEAR to NHSBT.	**None**
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.	This criterion is fully met. *Refer to assessment criterion S1.*	**None**
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.	This criterion is fully met. Transportation of organs retrieved by the NORS team is carried out by a specialist courier company. A transplant coordinator will be informed immediately of any delay or other cause for concern during transport.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
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.	This criterion is fully met. All healthcare personnel involved in transplantation are registered with the appropriate professional regulatory body and undertake continuing professional development to maintain their registration. Induction checklists and competence logs for some transplant coordinators and theatre staff were reviewed. Completion of formative and summative assessments is recorded in these logs. Junior surgeons joining the NORS team rota undergo a structured progression from observing retrievals, to assisting the lead surgeon, through to eventual sign-off of competence to lead at retrievals.	**None**
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.	This criterion is fully met. *Refer to assessment criterion GN1.*	**None**
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.	This criterion is fully met. Transplantation is a consultant-led service. The roles and responsibilities of staff involved in organ transplantation are defined in KCH.HTA.SOP.005 **'**Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation'.	**None**

Advice

No items of advice items were offered to the establishment.

Concluding comments

The establishment has met all of the applicable assessment criteria. Several areas of strength were identified. There was evidence of a strong team-working ethos and of clear communication between all staff involved in organ transplantation. In particular, the Transplant Services Manager plays a key role in ensuring the smooth operation of the Liver Transplant Unit. Documented operating procedures, which are based on the NOPs, reference all relevant forms and checklists. Donor technicians play a crucial role in providing operational support at NORS retrievals and act as a liaison between the retrieval team and the establishment. All living donors undergo a comprehensive psychiatric assessment prior to donation.

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

Report sent for factual accuracy: 10 October 2013

Report returned with comments: No comments on factual accuracy were received from the establishment

Final report issued: 28 October 2013

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.