Site visit audit report on compliance with HTA requirements

Cambridge University Hospitals NHS Foundation Trust

HTA licensing number 40032

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

07- 09 February 2017

Summary of Audit findings

Cambridge University Hospitals 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	Kidney	Pancreas	Liver	Small Bowel
Adult living	**DC, OC, P, T, R**		**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	Kidney	Pancreas	Liver	Small Bowel
Adult living	**OC, P, T, I**		**OC, P, T, I**	
Adult deceased	**OC, P, T, I**	**OC, P, T, I**	**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

Cambridge University Hospitals NHS Foundation Trust (CUH) has been licensed by the HTA since July 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 Addenbrooke's Hospital site in the Cambridge Transplant Centre. CUH currently undertakes

154 kidney transplants per year of which 53 are from living donors, 26 simultaneous pancreas and kidney transplants, 90 liver transplants and 9 multivisceral transplants (2015/16 data). Surgical procedures are carried out by a surgical team under the supervision of one of twelve consultant transplant surgeons; two consultant transplant surgeons are on call each day. The surgeons are experienced in all organ types. Surgery takes place in a dedicated theatre or in an emergency theatre if needed.

In October 2014, Addenbrooke's Hospital started using a proprietary electronic patient information system to record all clinical information. Records are linked to hospital medical record numbers (MRN), which act as patient identifiers. Use of the system is controlled with different levels of access permitted based on the role of the user.

Retrieval of Abdominal Organs from Deceased Donors

Surgeons based at CUH are commissioned by NHSBT as part of the National Organ Retrieval Service (NORS) to retrieve abdominal organs from deceased donors. On average, this NORS team attends around five donor hospitals every week and is on duty 52 weeks a year. Retrieval kits and organ boxes for liver, pancreas, kidneys and intestinal organs are stored in an area near the dedicated theatres. The kidney kits are bought ready made from a commercial supplier and supplementary materials and equipment are added to retrieval bags by the theatre team. The kits and boxes are checked daily to ensure that they are ready to go upon mobilisation of the team. Ice, frozen saline and perfusion fluids are stored nearby in a stock-controlled and temperature monitored fridge and freezer and added to the boxes when the team are mobilised. The NORS team is currently mobilised by a phone call from a specialist nurse for organ donation (SNOD) or the NHSBT Duty Office to the CUH RTC. The core CUH NORS team comprises of two surgeons, a scrub nurse and a perfusionist; the perfusionist's services are supplied under contract from a third party organisation.

The team meets the SNOD at the donor hospital and reviews paperwork including consent for donation and donor characterisation information. The retrieving surgeon also checks the clinical notes associated with the donor for any relevant history. Retrieval takes place after a team brief and once the surgeon confirms the identity of the donor. Following retrieval, the surgeons pack the organs in accordance with the national standards. Bowls are included to hold organs within the internal bags for liver and intestinal organs. SNODs label the transport boxes, ensure that the correct paperwork is present and that tissue samples have been included.The surgeon completes an NHSBT UK transplant registry donor information form for each organ noting the type and batch number of perfusion fluids, which come into contact with the organ, any organ damage and details of the organ's anatomy. For kidney and liver, this is the HTA A form and for pancreas this is the 'Deceased Donor Pancreas Information' form. The donor information form accompanies each organ to the respective transplant centre. If consent is in place and the donor hospital holds an HTA licence for removal of tissue under the Human Tissue Act 2004, kidney biopsies may be taken as part of the Quality in Organ Donation (QUOD) research project. This sample is packaged and transported along with the kidney. Organs which are to be transplanted at the CUH will accompany the NORS team back to base; NHSBT is responsible for transporting organs to other transplant centres.

Intestinal organs retrieved by the NORS team are always transplanted at CUH. The small bowel program at CUH includes intestinal alone, multi-visceral and modified multi-visceral transplants. On occasion, where consent is in place, abdominal fascia is retrieved along with the intestinal organs. Abdominal fascia is retrieved to facilitate closing the surgical opening in the recipient following intestinal transplant.

A consultant surgeon experienced in intestinal retrieval will always attend these retrievals and additional drugs required for preparing the donor will be taken by this surgeon. There is not a specific NHSBT UK transplant registry donor information form for intestinal organs and their retrieval is usually recorded using the deceased donor pancreas form (see advice item 2).

Deceased Donor Organ Transplants

Patients are only listed for transplant once they have met with a transplant surgeon and RTC. As part of the listing process, patients are given information about the transplant procedure including risks around different types of donors. Any restrictions on the type of donor that would be accepted by the potential recipient are recorded and updated periodically.

The Individual SNOD or the NHSBT Duty Office texts the on-call RTC to offer donor organs retrieved by the NORS teams. Organs may be offered to named recipients or to the establishment to determine a suitable recipient. The RTC logs into the NHSBT electronic offering system (EOS) to review the donor and organ characterisation information. Key details are recorded onto a pre-printed form which is used as an aide memoire when sharing the offer with the consultant surgeon responsible for implanting the organ. If the organ offer is potentially acceptable, the responsible surgeon uses the donor number to assess the characterisation information in EOS in more detail. Other clinicians such as a nephrologist or hepatologist are consulted as appropriate during the organ acceptance process. CUH are one of a group of four centres that are used by SNODs to screen potential donors with extended criteria to determine the feasibility of organ acceptance generally prior to approaching donor families.

Once the organ is accepted, a checklist is maintained by the RTC to ensure that key personnel and functions are informed, including the organ recipient. The RTC will add the donor to the electronic patient information system using their ODT number to produce an MRN. Two further identifiers are used so that the system can check for any existing records for this individual and avoid duplication of records.

The level of communication between RTC, implanting surgeon, retrieving surgeon and SNOD is organ specific. Kidney and pancreas implanting surgeons will wait for the organ(s) to arrive before commencing surgery. In the case of intestinal and liver transplants, the retrieving surgeon will usually contact the implanting surgeon upon visualisation of the organ to allow pre-emptive recipient surgery to begin and limit the cold ischaemic time of the organ. On arrival, organs are delivered to a theatre coordinator in the theatre area. Details of the organ, including the time and date of arrival, are recorded in the ‘Transplant Organ, Tissues and Vessels Register’ by the theatre coordinator accepting the organ. If the organ is a kidney then the level of ice within the box is checked to ensure that the organ is completely covered. The organ box is re-closed and stored on a specific shelf in the theatre area; other organs generally go straight into theatre for back-bench preparation. The ice level would be checked at the start of this bench preparation to ensure that the organs were transported appropriately. Blood for a repeat virology screen and blood, lymph and spleen for cross matching are removed from the box and placed in a labelled fridge for collection by the relevant laboratory staff. At the time of bench work, a sample of the transport perfusion fluid is taken and sent to microbiology. The sample orders are requested by the clinician under the donor details on the electronic patient information system using specific test requests.

The establishment also receives blood vessels (iliac veins, iliac arteries, carotid vessels, aorta). The vessels are retrieved alongside abdominal organs and used as conduits for vascular reconstruction during organ transplantation, in order to provide additional vessel length if required. Vessels which are not used to support organ transplantation for the designated recipient are placed in a lockable fridge located just outside the theatres. The vessels are then stored as human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (HTA Licence 11072).

There may be instances when an organ arriving at the establishment is rejected and the organ will require re-packing to enable it to be sent on to another recipient centre. In these cases the organ packing procedure, which establishment staff follow, is printed on the front cover of the bespoke 'Transplant organ tissue and vessels register' which has been produced by the establishment. This register is also used for recording the sending of an organ when it is taken to another recipient centre by NHSBT's courier.

Where appropriate an organ may be subject to ex-vivo normothermic perfusion as a part of a clinical trial at CUH. The equipment and consumables used for this procedure are CE marked.

Donors and recipients are linked in the electronic patient information system using the ODT number and MRN. Details of the transplant are captured on a transplant information page linked to each recipient. An amended version of the World Health Organisation (WHO) surgical checklist is held within the electronic system and is used to confirm the identity of the recipient. The HTA B form is filled in with details of the donor organ receipt, ODT number and HTA A number where applicable. Any surgical damage is noted, along with the batch number and type of any perfusion fluid that has come into contact with the organ after receipt. An HTA B form is filled in for each organ in a multivisceral transplant. For liver, kidney and pancreas transplants the RTC fills in a 'double-check' sheet that confirms that the HTA B form has been filled in correctly, the donor is linked to the recipient correctly in the electronic patient information system and the virology data is checked.

Completed HTA A and B forms are returned to NHSBT within seven days and a hard copy is retained at CUH. At around two days after transplant the RTC uploads a copy of the core donor data and the patient assessment form (PA1) onto the organ donor's electronic patient information area.

Living Donor Kidney Transplants

Potential living kidney donors are taken through a well-designed and documented pathway organised by living kidney coordinators. Work up of the potential donors may take place at CUH or two other local hospitals. In the case of overseas donors the initial work up may take place in their own country. Information and leaflets are given to the donor to ensure that, once accepted, the donors understand the procedures and risks involved. The pathway described in the establishment's procedures and checklists used by the living kidney coordinators ensure that the investigations necessary to confirm suitability to donate have been completed. HTA authorisation is sought once interviews with the Independent Assessor have taken place and donor nephrectomy takes place within a short period of time, usually within a few weeks. Two weeks before the scheduled transplant, tests such as blood group and virology are repeated regardless of where the initial work up was carried out. Consultant transplant surgeons and nephrologists contribute to the donor assessments and a final review of results and decision on the donor suitability to donate take place at a multidisciplinary team (MDT) meeting.

The recipient and the donor are scheduled to be in adjacent theatres and the electronic patient information system is used to access the WHO surgical checklist and confirm donor and recipient identities. If the organ is retrieved for paired/pooled living donations, the surgical team follow the documented procedure for packing the kidney before it is sent on to another transplant centres. NHSBT is responsible for making arrangements to transport the kidney to the recipient centre.

The donor is seen post-surgery and after six weeks by the transplant consultant. The establishment makes arrangements for on-going monitoring of the donor at a transplant clinic. The donor will be seen primarily by a transplant coordinator but the transplant consultant will

be available if there are any issues. A letter is sent to the donor's GP; this includes advice to contact the unit concerning any issues that may impact the organ recipient.

Living Donor Liver Transplants

Living donor liver transplants have taken place at CUH but only two have taken place to date. The establishment is currently promoting this as an option and are in the process of assessing potential donors. The living donor liver pathway is similar to the kidney pathway except that hepatologist assessment is included instead of nephrology.

Donor testing

The CUH transplant centre is supported by several services to allow for full donor characterisation. All requests for tests and subsequent reports of results are handled via the electronic patient information system.

The Department of Clinical Microbiology and Public Health Laboratory has CPA accreditation and are in the final stages of ISO1589 transition. The Department carries out donor serology tests for the full range of markers currently advised by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in their 2011 guidelines 'Microbiological Safety of Human Organs, Tissues and Cells'. Donor serology tests are carried out on living donors and samples of blood from deceased donors that are taken during organ retrieval. The latter are repeat tests of those carried out during the donor characterisation by NHSBT and, in response to correspondence with NHSBT, CUH have put in place a system to alert the duty office if any results do not correspond to those available on EOS for a particular donor. The Department also carries out tests to detect microorganisms which may be present in organ transport fluid so that recipients can be provided appropriate prophylaxis. Any positive results are flagged to the RTC and significantly positive results, interpreted by the establishment as those organisms that would require prophylaxis in the recipient, are reported to NHSBT so that the information can be shared with other transplant centres that have received organs from the same donor.

The Histocompatibility and Immunogenetics laboratory carry out HLA typing and monitor potential organ recipients at CUH for the presence of HLA specific antibodies. The laboratory is contacted when a deceased organ offer is accepted and will advise if they have sufficient data on the recipient to carry out a virtual cross match (six months of screening data and an antibody screen within the last three months). Recipients are asked about any recent potential sensitising events during a telephone call to discuss the organ offer. A wet cross match will be carried out if required before transplant and will always be carried out post transplant where the transplant has proceeded on a virtual match. The laboratory also carry out HLA typing and matching for living donor transplants.

There is also a 24 hr on call histopathology service at CUH that can be used if there are any anomalies in donor organs noticed during retrieval or bench work before transplant that need to be investigated histologically.

Tour of the Facilities and Roundtable Discussions

The audit consisted of a visual tour that followed the pathway of the organ from receipt at CUH through to the implanting theatre and of the donor testing laboratories outlined above. Roundtable discussions were held to discuss all of the activities carried out by CUH under licence 40032. The discussions were attended by a cross-section of staff involved in the transplant activities.

Document Review

A document review was carried out during the audit. Clinical notes relating to two deceased donor liver transplants, two deceased donor simultaneous pancreas and kidney transplants, two deceased donor liver transplants, one mulitivisceral transplant and one living donor/recipient kidney transplant were reviewed. Core Donor Data, HTA A forms, HTA B forms, details of perfusion fluids used, and RTC donor set up documents. The electronic patient information system was also reviewed for the correct donor, recipient and the presence of operation notes. There was a minor anomaly in one double check form; however, the electronic system was correct for this entry. There were some inconsistencies in the use of the HTA A form for multivisceral organs and in the use of the electronic patient information system for recording operation notes e.g. the correct version of the surgical checklist.

The accreditation status of the H&I laboratory, the Department of Clinical Microbiology, the histology service and the Sterile Services Department were reviewed and found to be suitable. The Trust wide Medical Devices Management Policy relating to the procurement of medical devices was reviewed; it was noted that the Trust only procured devices which were CE marked. Procedural documents such as NOPs linked to local procedures were reviewed.

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.	CT6	CUH have defined the 'implanting surgeon', in some written procedures, as the surgeon who makes the final decision to use an organ for transplantation. Depending on the organ, and the time between offer acceptance and implant, this surgeon may not be the surgeon responsible for performing the transplant operation. Relevant information from EOS and any communication with the retrieving surgeon will be relayed to the surgeon performing the transplant operation during handover meetings and/or the team brief held before implantation commences. The establishment is advised to be consistent in the definition of implanting surgeon in all written procedures and to describe, in an appropriate procedure, how they ensure that the appropriate surgeon has received all relevant information about the donor and donated organs at an appropriate time to allow a decision to be made on the organ's suitability for implantation. Currently the WHO transplant surgical checklist within the electronic patient information system allows the surgeon to record if EOS has been checked before implantation. However, there is an option to state that this has not taken place. Although this part of the checklist is not currently used the establishment is advised to remove this option.
2.	P3	There is not a specific HTA A form to use for intestinal organs and the establishment has used 'Deceased Donor Pancreas Information' forms (FRM 4122). Since these forms were not designed for intestinal organs they have been used inconsistently. The establishment is advised to decide on an appropriate and consistent way to use this form to record the retrieval of these organs or to use a different form to record the required information.
3.	TP1	The establishment is advised to include specific packing instructions for organs such as liver and intestines in their written procedures. This should include instructions for the packing of abdominal wall fascia.
4.	TC2	The electronic patient information system has the ability to trace back from recipient to donor via the transplant information page. The system will not, however, allow multiple organs received at CUH from an individual donor to be traced to all recipients. Although this can be achieved via other paper based routes, the establishment is advised to explore the possibility of achieving this through the electronic system since this is now the dominant system at CUH.
5.	TC2	The establishment is advised to find a way to improve the consistency of data entry into the electronic patient information system. Differences in the use of the system may lead to delays in sourcing information concerning donors and recipients.

Concluding comments

The Cambridge Transplant Unit is led by a team of Consultant Surgeons under the Direction of a Clinical Director. The Unit is supported by the Trust with access to dedicated theatres and the availability of a comprehensive histopathology service 24/7.

The receipt, use and distribution of organs is managed through the use of a log called the 'Transplant Organ, Tissues and Vessels Register'. The register allows clear traceability of the organs and also includes useful instructions for re-packing an organ box should an organ need to be re-directed to another centre.

The establishment is making progress with the relatively recent move to an electronic patient information system to record clinical information. Positive steps have been put in place to allow requests for analysis of donor samples to take place. The system has been adapted to allow the identification of key donor results by the appropriate personnel so that any results that need to be reported back to NHSBT can be sent quickly.

The establishment makes good use of checklists in the preparation of NORS kits, deceased donor acceptance and the living kidney donor pathway. The living kidney donor team knows the importance of donor follow-up. They take advantage of the donor work-up period for overseas donors to establish a line of communication with their clinicians, which will help during donor follow-up.

The Consultant surgeons are experienced across all organ types and provide supervision and training for Junior Doctors within the Unit. RTC training is particularly well documented with a competency pack that is used to record all aspects of training in the role.

The HTA has given advice to the establishment with respect to procedures for recording an organ's suitability for implantation, packing instructions and use of HTA A forms for intestinal organs and the use of the electronic patient information system.

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

Report sent for factual accuracy: 08 March 2017

Report returned with comments: 27 March 2017

Final report issued: 11 April 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.