Site visit audit report on compliance with HTA requirements

Leeds Teaching Hospitals NHS Trust

HTA licensing number 40040

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.

04-06 July 2017

Summary of Audit findings

Although the HTA found that Leeds Teaching Hospital (the establishment) had met the majority of the assessment criteria, one shortfall was found, in relation to organ preservation.

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	Composite tissue - Limbs
Adult living	**DC, OC, P, R**	**DC, OC, P, R**	**N/A**
Adult deceased	**DC, OC, P, R**	**DC, OC, P, R**	**DC, OC, P, R**
Paediatric deceased	**DC, OC, P, R**	**DC, OC, P, R**	**N/A**

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	Kidney	Composite tissue – Hand and upper limbs
Adult	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**
Paediatric	**OC, P, T, I**	**OC, P, T, I**	**N/A**

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

Leeds Teaching Hospitals NHS Trust (LTHT) has been licensed by the HTA since August 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 St James's University Hospital (SJUH) and Leeds General Infirmary (LGI).

Kidneys and livers from deceased donors are implanted into adults (at SJUH) and paediatric recipients (at LGI). Kidneys and liver lobes are also retrieved from living adult donors for implantation into adult and paediatric recipients. The establishment has also carried out a small number of hand and upper limb transplants.

The HTA licence held by LTHT for organ donation and transplantation activities is one of a number of HTA licences held by the Trust. The HTA licences are coordinated by an HTA Manager. The LTHT Transplant Unit has adopted and adapted the National Operating Procedures (NOPS). In addition the unit has a number of procedures and forms to ensure the consistent coordination of the Transplant Unit operations. There are regular multidisciplinary team meetings (MDT) to discuss all aspects of the pathway including decisions to accept or decline an organ. The Transplant Unit receives regular communications and feedback from NHSBT and shares the information appropriately with staff.

All laboratories that support the transplant unit are accredited by Clinical Pathology Accreditation (CPA) or United Kingdom Accreditation Service (UKAS). Tissue typing, virtual and wet cross matching takes place at the Histocompatibility and Immunogenetics Laboratory (H&I). The H&I laboratory follow a set of clear procedures to support decisions such as transplantation on the basis of virtual cross-match and the allocation of organs. The LTHT Cellular Pathology Department provides 24/7 on-call support for any histological investigations that are required by the Transplant Unit.

LTHT Pathology provides medical microbiology services to support transplant activities and is based at LGI. Tests for HIV 1/2, HBV, HCV, HTLV 1/2, CMV, EBV, syphilis and *Toxoplasma* are undertaken for living donors. In the case of deceased donations, the laboratory will undertake tests, in addition to those recorded in the Electronic Offering System (EOS), if requested by the surgeon e.g. Nucleic Acid Testing (NAT) where the donor was known to be an intravenous drug user. A sample of transport fluid which surrounds kidneys from deceased donors is sent to the microbiology laboratory for analysis. Surgeons 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.

<u>Retrieval of Abdominal Organs from Deceased donors</u>

Surgeons based at SJUH are commissioned by NHSBT as part of the National Organ Retrieval Service (NORS) to retrieve abdominal organs from deceased adult and paediatric donors. The team are one of only three teams able to carry out paediatric liver retrievals. On average, this NORS team attends around five donor hospitals every week and shares a one week on, one week off rota in conjunction with a NORS team linked to another HTA licensed establishment. The establishment uses NHSBT's transport provider who attends the hospital to meet the retrieval team and is trained to assist with preparation of items that need to be taken out on a retrieval. Responsibility for the materials, equipment and reagents that need to be ready for a NORS team retrieval is shared between the Transplant Coordinators, NORS Scrub Nurse, Pharmacy Services and the transport provider. The items are all stored in secure, temperature-controlled environments and a series of checklists are available to ensure everything that is needed is taken out on retrieval. The team has recently started to use NHSBT's new kidney transport boxes. Training in the use of these boxes has been

cascaded across the transplantation team and initial difficulties with the boxes have been reported to NHSBT as appropriate.

The Leeds NORS team typically consists of a lead surgeon, assistant surgeon and scrub nurse. A paediatric specialist consultant will attend paediatric retrievals. The team meets the specialist nurse in organ donation (SNOD) at the donor hospital and reviews paperwork including consent for donation and donor characterisation information. 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. Photographs of the organs are taken by the SNOD to aid decision making by the accepting centres. 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. 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 that are to be transplanted at the SJUH will accompany the NORS team back to base; NHSBT is responsible for transporting organs to other transplant centres.

Deceased Donor Organ Transplants

The establishment has a procedure to ensure that potential recipients of liver or kidney transplants are kept aware of the risks and benefits of transplantation and that their consent is up to date. The procedure includes regular contact with patients from the point of listing on the national waiting list until the time of offering and transplantation.

The Individual SNOD or the NHSBT Duty Office texts the on-call Recipient Transplant Coordinator (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 EOS to review the donor and organ characterisation information. Key details are recorded onto a pre-printed form that is used as an aide memoire when sharing the offer with the consultant surgeon responsible for accepting 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, hepatologist or virologist are consulted as appropriate during the organ acceptance process.

Once the organ is accepted, a checklist is maintained by the RTC to ensure that key personnel and functions are informed. An emphasis is placed on ensuring the transplant can take place with minimal delay. Communication is organ specific. The H&I laboratory are highly involved with the acceptance of kidneys; this may be in the identification of appropriate recipients in the case of local allocation or in establishing the requirement for a cross match. In the case of 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.

All organs are benched at SJUH before transplant, even when transplant is for paediatric patients and will take place at LGI. Upon arrival livers are taken directly to theatre and benching is commenced. Kidneys are taken to a secure transplant room where they can be stored before benching and between benching and transplant. Kidneys may need to be stored for longer where a cross match is required. A check is carried out upon arrival to ensure that packaging and ice levels are satisfactory and a form is used to log the movement of the kidney and the transfer of blood, lymph and spleen samples to the H&I laboratory. The establishment use machine perfusion on occasion to preserve kidneys including neonatal

kidneys. The machines are stored in the transplant room ready for use and are used under the supervision of a trained transplant consultant. The liver team also participate in a trial for the use of normothermic perfusion when the donor meets the requirements of the trial protocol and consent is in place.

An amended version of the World Health Organisation (WHO) surgical checklist is used in theatre; the checklist includes a final check on the donor characterisation. Where the accepting surgeon and the implanting surgeon are not the same this information will also be discussed during handover. The HTA B form is filled in with details of the donor organ receipt, ODT number and HTA A number. 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.

Organs used for paediatric transplant are receipted and benched at SJUH and are then taken directly to theatre at LGI. There is a small stock of perfusion fluid and frozen saline kept adjacent to the theatres at LGI (see advice item 3)

There may be instances when an organ arriving at the establishment is deemed unsuitable for transplantation after receipt at LTHT Where appropriate the organ may be considered by the NHSBT Duty Office for fast-track offers to other centres, be used for research where appropriate consent is in place or sent for disposal. The final use of all organs is clearly documented by the establishment.

Deceased Upper Limb Transplants

LTHT have a hand and upper limb transplant (HAUL) programme. This is a unique programme in the UK and has been introduced with careful consideration of the impact on solid organ donation and the need for specific training of SNODs. SNODs that are associated with hospitals participating in the HAUL donation programme have been provided with detailed information about the transplantation process, donor identification and the particular sensitivities of obtaining consent for HAUL donation. Physical matching of donor and recipient is an important factor and SNODs are provided with the information they need for initial identification of a donor. Final decisions on matching are made by the HAUL Clinical Lead who knows the detailed requirements of the recipients.

Potential recipients of HAUL transplants are added to the waiting list after extensive consultation following a detailed pathway. Potential recipients are referred from a variety of avenues including self-referral and attend quarterly HAUL clinics. The clinics are attended by professionals from a variety of backgrounds including plastic surgeons, physiotherapists, psychiatrists and prosthetic specialists. Recipients are given the opportunity to discuss other routes to improve their experience of living with HAUL disabilities. Individuals that go on to be listed are provided with information and support to prepare them for their potential transplant.

When a donor has been identified, and the required pre-operative tests and tissue typing have been completed, a member of the HAUL surgical team will attend the donor hospital along with the Leeds NORS team. The HAUL surgeons take part in all of the usual retrieval preparations along with the SNOD and NORS team. The team ensure that the HAUL retrieval process has minimal impact on the solid organ retrieval process. The dignity of the donor is respected and the team endeavour to restore the appearance of the donor in line with their family's wishes.

The HAUL programme has detailed procedures for the retrieval and organ pathway. This includes instructions for packing the organ(s) and traceability via HTA-A and B forms. The retrieval surgeon accompanies the organ(s) from retrieval to transplantation.

Living Donor Transplants

LTHT has well-established programmes for the donation of liver lobes and kidneys from living donors. For both organs there is a well-defined pathway to determine the eligibility of the

donors and ensure informed consent. Potential donors are provided with the information they need to weigh up the risks of donation. Information is provided in the form of literature and donors are given access to a variety of health professionals such as transplant coordinators, consultant surgeons, hepatologists, nephrologists, psychiatrists and social workers. The social and medical history of the potential donor is examined and virology testing, scans and screening tests are undertaken early on in the pathway. Critical tests are repeated in the week preceding the actual donation to ensure that information is current.

The recipient and the donor are scheduled to be in adjacent (side by side or across a corridor) theatres and WHO surgical safety checklists are completed before knife to skin. In the case of liver lobe donation for a paediatric patient the donor surgical team maintain regular telephone contact with the recipient surgical team especially before irreversible steps are taken. If a kidney is retrieved for paired/pooled living donation, the surgical team follow the documented procedure for packing the kidney before it is sent on to another transplant centre. NHSBT is responsible for making arrangements to transport the kidney to the recipient centre.

The establishment makes arrangements for on-going monitoring of the donor. A letter is sent to the donor's GP. The centre provides information to the donor regarding the importance of follow up appointments and annual checks.

Tour of the Facilities and Roundtable Discussions

The audit consisted of a visual tour that followed the pathway of the organ from receipt at SJUH through to the implanting theatre at SJUH or LGI. The Virology, H&I and Histology Laboratories were visited and the audit team met with transport providers and viewed the vehicles used to transport NORs teams and organs. Roundtable discussions were held to discuss all of the activities carried out by LTHT under licence 40040. 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. Transplant records relating to two deceased donor kidney transplants for adults, three deceased donor kidney transplants for children, one deceased donor liver transplant for an adult, one deceased liver and kidney transplant for an adult, and one split liver transplant for a paediatric case. Core Donor Data, consent forms, HTA B forms, Deceased Kidney Donor Materials for Transplant Immunology forms, Benching forms, clerking notes and H&I results were all examined.

The accreditation status of the relevant services 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

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.	Machine perfusion for neonate kidneys is carried out in a machine that was not intended for this purpose by its manufacturers. There has been close collaboration between SJUH and the machine manufacturers concerning this use, however, a documented risk assessment has not been produced. The Trust's Medical devices Management Policy requires a risk assessment to be documented whenever a device is used outside its intended purpose.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	CT3	The establishment provided a copy of a proposed new 'streamlined' medical history form for use in the living kidney donor pathway. The establishment is advised to review the proposed form to ensure that all behavioural risks that may imply the risk of disease transmission have been captured.
2.	P1	The establishment has three machines available for machine perfusion. The establishment is advised to record an identifier for the machine used in preservation of a particular organ in an appropriate place in the current transplantation records. This will allow for traceability and follow-up should there be any issues with the machine.
3.	P1	The establishment has a well-developed system at SJUH to ensure the appropriate storage of perfusion fluids and frozen saline. Members of the Transplant Unit and Pharmacy ensure that there are adequate in-date stocks and that the temperature of the fridges and freezers are monitored daily. The establishment is advised to review the management of perfusion fluids and frozen saline at LGI for use in paediatric transplants.
4.	P3	The establishment notes the batches of perfusion fluid used during the benching of organs in its own 'benching forms'; the batches of perfusion fluid are also noted on the HTA-B forms that are returned to NHSBT. Two examples were found where perfusion fluid was noted on the benching form but not on the HTA-B form. The establishment is advised to look into ways to ensure that the perfusion fluid is always added to the HTA-B form. A cross-check against the benching form may assist with this.
5.	I2	The establishment should consider revising the form 'Deceased Donor Kidney Materials for Transplant Immunology' since examples of the form viewed during the audit were completed inconsistently in the fields intended to track movement of organs between the transplant room and theatre and the laboratory section filled in by the H&I staff.
6.	S3	The establishment should consider including the Virology, H&I and Histopathology Laboratories in the distribution of the SOP 'Reporting an incident and governance arrangements for organ donation and transplantation'.
7.	GN1	The establishment has stated in the SOP 'Organ Retrieval (Live and Deceased) and Transplantation' that all staff will be trained in the management of the machine perfusion devices and signed off as safe to use the equipment. The audit team were informed that this process always takes place under the supervision of a trained consultant surgeon; however, there were no written records of this training. The establishment is advised to document the training for use of this device.

Concluding comments

The LTHT Transplant Unit is led by Consultant Surgeons and supported by a team of

dedicated and knowledgeable staff. The work of the Unit is also supported by a range of other services within the Trust such as the H&I, Virology and Histology Laboratories and a range of theatre staff. There is an HTA Manager who assists with compliance and provides overall consistency amongst all of the HTA licences held by LTHT.

The pathway for organs received at the Trust is controlled and there are detailed instructions provided for staff where need is anticipated e.g. on the use of the new NHSBT kidney boxes and for the transport providers assisting with NORS preparation. Written procedures are clear and good use is made of flowcharts and checklists. The live donor liver transplant protocol is particularly well-defined and provides a comprehensive description of the donation process. Procedures within the H&I laboratory supporting transplant decisions are also well documented.

Communications from NHSBT are generally put to good use within the unit sometimes via presentations; feedback from incidents is acted upon and shared with staff.

It was apparent that considerable thought has been given to the HAUL procedures The HAUL programme has benefited from the experience of the staff involved in kidney and liver transplants and there is evidence that there is an excellent level of communication between the teams.

One area of practice was identified during the course of the inspection that requires improvement, and this has resulted in one minor shortfall. The HTA has given advice to the establishment with respect to living donor assessment, perfusion fluid storage, consistent record keeping and distribution of an SOP.

The HTA requires that the establishment addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfall identified during the audit.

Report sent for factual accuracy: 02 August 2017

Report returned with comments: No factual accuracy or request for redaction comments were made by the establishment

Final report issued: 05 September 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 17 November 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.