Site visit audit report on compliance with HTA requirements

Guy's and St Thomas' Foundation NHS Trust

HTA licensing number 40029

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

13-14 December 2017

Summary of Audit findings

Although the HTA found that Guy's and St Thomas' Foundation NHS Trust (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to living donor characterisation.

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

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria:

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.

Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 1: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Licensable activities carried out by the establishment – Procurement activities

Organ type	Kidney
Adult living	**DC, OC, P, 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
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

Guy's and St Thomas' NHS Foundation Trust (GSTT) (the establishment) carries out kidney and pancreas transplants. These can be kidney only, pancreas only, simultaneous pancreas-kidney (SPK) or pancreas after kidney (PAK) procedures.

Transplant activity for adult patients takes place at Guy's Hospital. Organs for paediatric recipients are implanted at Evelina Children's Hospital, situated at the St Thomas' Hospital site. Donor and organ characterisation tests, other than those undertaken by NHS Blood and Transplant (NHSBT) for deceased donors, are performed by the establishment's laboratories.

Surgeons hold honorary contracts with Great Ormond Street Hospital (HTA licensing number 40041) to implant organs at that establishment under their HTA licence. Adult live donor kidneys for implantation at Great Ormond Street Hospital are procured at Guy's Hospital.

All laboratories that support the transplant unit are accredited by Clinical Pathology Accreditation (CPA) or United Kingdom Accreditation Service (UKAS). Tissue typing, virtual and formal cross matching takes place at the establishment's Clinical Transplantation Laboratory. This laboratory provides histocompatibility and immunogenetics (H&I) testing services for King's College, St George's and Great Ormond Street Hospitals. The establishment routinely requests a peripheral blood sample for testing before transplantation where a formal cross-match is required. Other transplants are carried out on the basis of a virtual cross-match with a wet cross-match taking place post-transplant. The GSTT Histopathology Department provides cover during the day Monday to Friday for any histological investigations that are required by the Transplant Unit. Investigations outside this timeframe require collaboration with other units that have a wider availability of service - usually a liver unit.

Virology and Microbiology tests are carried out by the GSTT Infection Sciences Service. Tests for HIV 1/2, HBV, HCV, HTLV 1/2, CMV, EBV, HEV, 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>Deceased Donor Organ Transplants</u>

The establishment employs ten transplant surgeons, who receive offers of organs from NHSBT on an on-call rota; two surgeons are on the rota to receive offers at any one time. The surgeon logs into NHSBT's EOS to review the donor and organ characterisation information. Organs are offered to named recipients and other clinicians such as a nephrologist or virologist are consulted as appropriate during the organ acceptance process.

Once the organ is accepted, the surgeon communicates with the dedicated renal transplant ward to prepare for the incoming recipient patient and with the H&I laboratory to determine the need for a wet cross match. An emphasis is placed on ensuring the transplant can take place with minimal delay. Organs are delivered by courier to the Richard Bright Ward and collected by a surgeon to be taken to theatre. A logbook is used to track the movement of the organs in and out of Richard Bright Ward. Organs used for paediatric transplant are receipted and benched at the Evelina Hospital. A logbook has recently been introduced to track the movement of organs in and out of this hospital. Advice has been given to ensure that packaging and in particular, ice levels are checked on receipted organs should a transplant be delayed (see *Advice*, item 4).

An amended version of the World Health Organisation (WHO) surgical checklist is used in theatre at GSTT; 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 form 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 following receipt at the establishment.

There may be instances when an organ arriving at the establishment is deemed unsuitable for transplantation after receipt. 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 using logbooks at Guy's or the Evelina Hospitals.

The team at GSTT have facilitated kidney transplants for HIV-infected reciepients; this is the first centre in the UK to make such transplants available.

Living Donation

The establishment retrieves kidneys from living donors for adult and paediatric recipients. Potential kidney donors are provided with information that explains the procedure and risks involved in kidney donation. The establishment tries to ensure that donor work-up can take place at a hospital located close to where the donor lives. A proportion of donors come from outside the UK and the living kidney donor transplantation team work carefully to assess them and ensure that essential post-donation clinical care and follow-up is available and affordable for the potential overseas donor. There are several stages involved in the donor work-up and donors are assessed by clinicians from a number of disciplines. The establishment's 'ABC' patient workup sheet provides details of a donor's progress through the pathway including appointments with the nephrologist and the surgeon. In all cases, the final stages of donor work up take place at Guy's Hospital. A living kidney donor meeting is held every week and is attended by coordinators, surgeons, nephrologists and staff from the H&I Laboratory. Decisions made at the meetings are documented in the electronic patient records.

Potential living kidney donors are assessed for their suitability to donate but this does not include a robust review of the likelihood that they have been exposed to infection risks. For example, donors are not asked to provide details of behavioural and travel history including specific questions regarding past or present use of IV drugs (see shortfall below).

Formal consent for the removal of a kidney is sought from the donor once a detailed medical evaluation takes place and HTA approval is obtained.

Mandatory virology tests, and other critical clinical tests, are repeated within 28 days before donation. The date of surgery is scheduled, and donors and recipients are admitted into the hospital. Donors are re-consented and checks carried out on the identity of the donor before the kidney is retrieved.

If a kidney is retrieved for paired/pooled living donation, or for transplantation at another hospital such as the Evelina or GOSH, the surgical team follow a documented procedure for packing the kidney before it is transported. NHSBT is responsible for making arrangements to transport the kidney to the recipient centre in the case of paired/pooled living donation. Organs transported to GOSH or Evelina are accompanied by the transplant surgeon.

The establishment makes arrangements for on-going monitoring of the donor following their surgery. A letter is sent to the donor's GP or to the referral centre overseas. The living kidney donor transplantation team provide 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 tour that followed the pathway of the organ from receipt at Guy's or the Evelina Hospital through to the implanting theatre. The H&I Laboratory at Guy's was visited. Roundtable discussions were held to discuss all of the transplant activities carried out under licence 40029. 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 and two living donor kidney transplants for adults, and one deceased and one living donor kidney transplant for children, were reviewed. Data was checked using the electronic patient records.

The accreditation status of the relevant laboratory services were reviewed and found to be suitable. The Trust-wide Medical Devices Management Policy relating to the procurement of medical devices was reviewed and found to be appropriate. Procedural documents, such as National Operating Procedures (NOPs) linked to local procedures, were reviewed.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive. **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.	The establishment does not seek information from living donors about behaviour such as therapies involving penetration by needles or recent travel history to areas of high infection risk, in order to assess the possible risk of transmitting infections to the recipient. This information will inform the need to test for infectious diseases in addition to mandatory testing for HIV, HBV and HCV. Information on current and past IV drug use is not recorded.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	CT4	The establishment is currently taking part in a clinical trial during which organs are mechanically perfused prior to their implantation. 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.	I1	The establishment uses a modified version of the WHO checklist to allow formal acknowledgement of the recipient cross-match result. This acknowledgment is not consistently filled in by surgeons as evidenced by several checklists viewed during the audit. The establishment is advised to ensure that the cross match acknowledgment on the checklist is clear and understood by all staff. In addition, the establishment should consider carrying out their own periodic audits of the checklists.
3.	I1	Characterisation and approval of adult living kidney donors takes place at Guy's Hospital following a well-defined pathway. The establishment is advised to introduce a formal step to allow implanting surgeons at the Evelina Hospital to acknowledge that they have received all relevant information concerning donor characterisation before implanting an organ into a paediatric recipient.
4.	I2	The establishment makes every effort to ensure that received organs are transplanted with minimal delay. Organs are moved quickly from their point of receipt to theatre where appropriate packaging, including sufficiency of ice levels, is checked during the back bench preparation of the organ. The establishment should consider introducing a mechanism to ensure that checks on packaging, including ice levels, are made should a delay in transplant occur.
5.	TP1	The establishment is advised to introduce a method of tracking the movement of organs from living donors that are sent directly from theatre at Guy's Hospital to other establishments such as the Evelina Hospital. All other movements of organs in and out of the establishment are tracked in a logbook held in the renal transplant ward.
6.	S2	The establishment is advised to provide guidance to staff involved in incident assessment on the definition of serious adverse events and reactions that are reportable to NHSBT and the procedure for doing this. This could be achieved by referencing SOP 3888/2, available from

No.	Assessment Criterion	Advice
		NHSBT, within the Trust's own policy on incident reporting and management.
7.	GN1	The current living donor coordinators have been in post for some time and have considerable experience of the living donor pathway. The establishment is advised to consider developing a set of competencies for this role to capture the training needs for staff recruited to this role in the future.

Concluding comments

The transplant activities at GSTT are led by a team of surgeons and supported by dedicated staff within the transplant wards, theatres and associated laboratories. The governance lead, a Consultant Surgeon, conveyed the great level of respect that is afforded to donors and donated organs at this centre. Since the last audit, the establishment has improved the systems that are used to control the return of HTA-A and B forms to NHSBT. This is now under the control of a recipient coordinator and a spread sheet is used to ensure that forms have been returned. There is good use of paperwork to ensure that documents within the pathway are completed correctly or that the pathway is understood by the living donor including: a laminated script that is used to quickly spot and amend errors in transplant forms and a flow diagram to show living donors how far along the donor pathway they are.

There was one minor shortfall associated with donor characterisation and the HTA has given advice to the establishment with respect to record retention for clinical trials, recording of key activities with respect to surgeon's responsibilities, checking of packaging in case of transplant delay, incident reporting and the recording of staff competencies for future coordinators.

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: 12 January 2018

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

Final report issued: 20 February 2018

Completion of corrective and preventative actions (CAPA) plan

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

Date: 31 October 2019

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.