Site visit audit report on compliance with HTA requirements

HCA International Ltd

HTA licensing number 40036

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

28 March 2018

Summary of Audit findings

Although the HTA found that HCA International Ltd (the establishment) had met the majority of the assessment criteria, one shortfall was found, in relation to 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	**DC, OC, P, T and R**
Liver	**DC, OC, P, T and 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 – Transplantation activities

Organ type	
Kidney	**OC, P, T and I**
Liver	**OC, P, T and 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

HCA International Ltd 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 London Bridge Hospital.

Kidneys and liver lobes are retrieved from living adult donors for implantation into adult and paediatric recipients. Paediatric recipients are transplanted at other licensed specialist centres. Donor and recipient pairs are generally from overseas and referred directly to the establishment from overseas healthcare institutions or through their foreign embassies.

The London Bridge Hospital Transplantation Surgery Unit has a full time transplant co-ordinator to provide support for the transplantation pathway. Consultant surgeons and other specialists such as consultant nephrologists and hepatologists have practising privileges at the establishment.

Initially, following the referral of a potential donor and recipient pair, the transplant consultants will review the medical information that has been provided by the referring centre. If both the donor and recipient are found to be suitable at this stage, the donor work up will commence.

For both liver lobes and kidneys 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. Written information is provided in the form of literature and donors are given access to a variety of healthcare professionals such as transplant coordinators, consultant surgeons, hepatologists, nephrologists and psychiatrists.

As part of the donor work-up, donor and organ characterisation tests that have taken place in the donor's home country are repeated by the establishment. These tests include the mandatory serological screens and other mandatory organ and donor characterisation assessments. Multidisciplinary team meetings (MDT), involving additional medics who contribute to the donor and recipient assessment process, are part of the transplantation pathway. The London Bridge Hospital Transplantation Surgery 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 Transplantation Surgery Unit operations.

If the donor is clinically suitable, the transplant surgery is scheduled and the donor and recipient are interviewed by an Independent Assessor. Transplant surgery usually takes place on a Saturday which is a time when the establishment's demand for theatres is reduced meaning the surgery can take place in adjacent theatres. An amended version of the World Health Organisation (WHO) surgical checklist is used in theatre. Stocks of perfusion fluids used during organ retrieval and transplant are kept in temperature-monitored fridges and brought into theatre on the day of the transplant. The consultant surgeon completes the HTA-A and HTA-B forms. The transplant co-ordinator scans and sends the forms to NHSBT ensuring they arrive within seven days; hard copies of the forms are sent later.

All laboratories that support the transplantation programme are accredited by Clinical Pathology Accreditation (CPA) or United Kingdom Accreditation Service (UKAS). Tissue typing and histology take place in laboratories at other HTA-licensed establishments. Two HCA laboratories at Shropshire House and Wimpole Street carry out tests for HIV 1/2, HBV, HCV, HTLV 1/2, CMV, EBV, syphilis and *Toxoplasma.*

Following surgery, the donor is reviewed by the surgeon and is seen again at ten days after surgery and finally at around eight weeks. Following these consultations, if there are no complications arising following surgery, the donor returns to their home country where they are routinely discharged to a consultant at a transplant centre located there. The consultant in

the donor's home country is sent relevant clinical details relating to the donor including a summary report.

Tour of the Facilities and Roundtable Discussions

The audit consisted of a visual tour of the operating theatres and perfusion fluid storage areas. Roundtable discussions were held to discuss the activities carried out by HCA International Ltd under licence 40036. 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 living liver and two living kidney transplants were reviewed. Records included: consent forms, donor medical history, donor evaluation, MDT summary, HTA A and B forms and serology results.

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. A series of procedural documents linked to local procedures were also 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 ensure that donor characterisation is in line with British Transplantation Society or The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) guidelines as the unit does not ensure that a blood sample is tested for HIV, HBV and HCV within 30 days (before organ donation). 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.	CT2	The establishment is advised to add a prompt to the renal medical history form to ensure that any potential risks in terms of infections that may be acquired through travel are captured.
2.	R4	Donors generally return to the care of healthcare professionals within their own country and clinicians are provided with a summary report of the hepatectomy or nephrectomy. The establishment is advised to ensure that, in addition, information will be provided advising the donor to inform their local transplant clinician in case of events or reactions that may have a consequence for the organ recipient. The local clinician will in turn contact the transplant unit at The London Bridge Hospital
3.	S2	The establishment is advised to add the requirement to report serious adverse events and reactions to NHSBT within 24 hrs to the SOP entitled 'Reporting an organ donation or transplant incident to NHSBT'.
4.	GN1	The current transplant co-ordinator has been in post for some time and has 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 living donor pathway at HCA International Ltd is well-defined and a consistent approach to record-keeping is ensured by the role of transplant co-ordinator for liver and kidney transplants. Consultants employed in the Transplantation Surgery Unit are experienced in the transplant field and their practicing privileges are renewed annually. There is a strong commitment to providing living donors with the information and support they need to make informed decisions about consenting to organ donation.

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, follow-up of living donors, SAEARs reporting and training.

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: 17 April 2018

Report returned with comments: 30 April 2018

Final report issued: 01 May 2018

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: 02 August 2018

Appendix: Classification of the level of shortfall

Where the HTA determines that an assessment criterion is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an assessment criterion, it works on the premise that a lack of evidence indicates a shortfall.
The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to the quality of an organ intended for transplantation or which poses a significant direct risk of causing harm to a donor or recipient.

Or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient;

or

A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting quality and safety of an organ intended for transplantation or the safety of a donor or recipient;

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final audit report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next audit.
In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final audit report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final audit report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.
Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

 a follow-up audit

 a request for information that shows completion of actions

 monitoring of the action plan completion

 follow up at next desk-based or site-visit audit.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.