Site visit audit report on compliance with HTA requirements

London Independent Hospital

HTA licensing number 40067

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), retrieval of an organ (R)**

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), implantation of an organ (I)**

Under the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

10 September 2013

Summary of Audit findings

The London Independent Hospital BMI (the establishment) was found to have met all applicable assessment criteria. The establishment were given advice in respect to document control and ensuring that the roles and responsibilities of all individuals involved in licensed activities are clearly defined.

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, 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
Adult living	**OC, P, 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

The London Independent Hospital (the establishment) HTA licence (40067) have recently implemented a living donor kidney programme. This programme has been developed for a limited patient group; overseas donor and recipient pairs will be referred through foreign embassies with which the establishment already have close ties. The establishment require a two-week lead up to the potential donation and transplant and have a surgeon led standard pathway which will be followed each time a referral is made. For each referral, patient notes are assessed prior to the donor and recipient attending outpatient assessment at the establishment.

Once deemed clinically suitable for transplantation, the donor and recipient are referred to independent assessors.

The establishment will perform concurrent retrieval and transplantation in adjacent theatres.

The potential donor requires a letter from a physician to confirm that they will receive care following the donation. The donor is seen in clinic ten days post operatively and then again at six weeks. A letter to the referring physician instructs six month and yearly check-ups.

All laboratories that conduct donor and organ characterisation testing on behalf of the establishment are accredited by Clinical Pathology Accreditation (UK) Ltd (CPA). The establishment are working on an interface with the testing laboratories which will allow the electronic submission of test results.

The establishment has adopted all the relevant national operating procedures (NOPs) and, from these, developed a single standard operating procedure (SOP) to describe the establishment's transplant protocols. The establishment also use a pathway document to reflect local practice.

To date, the establishment have had one referral which did not proceed.

This first, routine site visit included a tour of the premises, document review, and round-table discussions with the establishment's staff.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.	This criterion does not apply to the establishment.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. The retrieving surgeon is responsible for filling out HTA A and HTA B forms. During the inspection it was unclear as to who would be returning these forms to NHSBT and advice has been provided. All mandatory and complementary donor tests are carried out as part of living donor work up.	**None**
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.	Where it is considered appropriate the information specified in Part B of the Annex to the Directive will be collected.	**None**
CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Documentation reviewed was not specific in regards to retention of records for 30 years but did say that health records will be retained for 8 years after conclusion of treatment or death. Advice and guidance was provided to ensure that patient records are maintained for 30 years as required by the regulations.	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. All tests carried are performed by CPA accredited laboratories and relevant certificates were seen for histology, virology, histocompatibility and immunogenetics and serology. The establishment is looking to interphase with the internal electronic reporting of the testing laboratories to streamline data reports.	**None**
CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Both retrieving and implanting surgeons are involved in donor and recipient work-up. Donation and transplantation will be performed concurrently in adjoining theatres.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Retrieval of Organs for transplantation		
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.	This criterion was not assessed as the establishment have not yet performed any transplants. Donor consent will be sought by the retrieving surgeon.	**None**
R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has a policy that no contract will be agreed unless due diligence has been undertaken by the procurement department to ensure that all products have relevant accreditation e.g. CE markings.	**None**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. All surgical instruments are sent off-site for cleaning and sterilisation. BSI certificates of registration QMS ISO 13485:2003 were seen. Photographs are taken of all surgical kits sent so that there are no misunderstandings on what should be returned. These photographs are also useful for surgeons who have a visual check of what is available to them in theatre.	**None**

R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.	This criterion is fully met. Where the donor is from overseas the referring physician will be advised on how to care for the donor and that the transplant team are available for further advice. The potential donor requires a letter from a physician to confirm that they will receive care following the donation. The donor is seen in clinic 10 days post operatively and then again at 6 weeks. A letter to the referring physician instructs 6 month and yearly check-ups. Advice and guidance was provided to the establishment as it was unclear whether the donor follow up letter would state the requirement to report serious adverse events or adverse reactions (SAEARs) relating to organ donation.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has a policy for the maintenance of biomedical equipment; which states that service must be compliant with BD2006 (05) ISO 13485:2003. Perfusion fluid will be ordered as required and stored in a theatre fridge.	**None**
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. All surgical instruments are sent off-site for cleaning and sterilisation. BSI certificates of registration QMS ISO 13485:2003 were seen.	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion was not assessed as the establishment has not yet conducted any transplants. The retrieving surgeon will be responsible for the completion of HTA A and B forms.	**N/A**

Assessment Criteria	Audit findings	Level of Shortfall
Making arrangements to transport an organ		
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criteria is not applicable to the establishment as retrieval and transplantation will occur concurrently in adjacent theatres	**N/A**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criteria is not applicable to the establishment as retrieval and transplantation will occur concurrently in adjacent theatres	**N/A**
TP3) The organ shipping container used for transporting organs from the licensed premises is labeled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criteria is not applicable to the establishment as retrieval and transplantation will occur concurrently in adjacent theatres	**N/A**
TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criteria is not applicable to the establishment as retrieval and transplantation will occur concurrently in adjacent theatres	**N/A**
TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.	This criteria is not applicable to the establishment as retrieval and transplantation will occur concurrently in adjacent theatres	**N/A**

Assessment Criteria	Audit findings	Level of Shortfall
Implantation		
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Both the retrieving and transplanting surgeons will be involved in donor workup. A donor workup schedule and a pre-operative checklist are in place. Only one donor and recipient pair will be involved in surgery at any one time.	**None**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion was not assessed as the establishment has not yet performed any transplants.	**N/A**
I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.	This criterion is fully met. The transplant lead will ensure that all decisions relating to risk and benefit choices are recorded in patient notes.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment's SOP is unclear as to who will complete and return the HTA forms although the surgeons will be responsible for their completion. Advice and guidance was provided	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. Three forms of identification are used: the patient's hospital number, full name and date of birth.	**None**
TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.	Transportation of organs to or from the establishment is not expected to occur at the establishment.	**N/A**

Assessment Criteria	Audit findings	Level of Shortfall
Serious adverse events and reactions (SAEARs) – (*these criteria apply to all licensed activities*)		
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.	This criterion is fully met. The establishment have a policy on quality and risk incident reporting and investigation. The incident is recorded at the time by the most senior member of staff available at the time. All serious incidents are bought to the attention of Facilities Director and the Executive Director. The transplant lead is responsible for reporting all SAEARs to NHSBT but this is not clear in the establishment's documentation; advice and guidance has been provided.	**None**
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	The establishment's unified SOP refers to NHSBT's SOP3888/1 on reporting organ donation or transplantation incidents to NHSBT, and describes that the Transplant Service Lead and the Transplant team will be responsible for incident reporting. Staff at the establishment understand the SAEARs reporting requirement and procedure, and that a SAEAR must be reported to NHSBT within 24 hours of its discovery. However, this 24-hour reporting requirement is not stated explicitly in the unified SOP.	**Minor**
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.	This criterion is fully met. Donor and organ characterisation testing is carried out either by a laboratory onsite or by a laboratory at another HTA-licensed organ transplant centre (specifically for virology, and for histocompatibility and immunogenetics – H&I – testing). All laboratories have full CPA (UK) accreditation. Staff at the onsite testing laboratory would report any errors in donor testing results directly to the consultant surgeon.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
General – (*these criteria apply to all licensed activities*)		
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.	This criterion is fully met. The establishment have a policy for induction which includes mandatory training and additional e-learning. Surgeons have practising privileges.	**None**
GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.	The establishment has a development policy specifically for staff to develop a learning development plan	**None**
GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.	This criterion is fully met. All transplant activities will be conducted under the supervision of two highly experienced surgeons.	**None**

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 formally document the roles and responsibilities of those involved in the organ donation and transplantation procedures. An organogram may assist in clearly defining roles and responsibilities and also contingency for sickness and absence.
2.	CT4	The establishment is advised that it is a requirement under the regulations to ensure that patient records are maintained for 30 years and that the records retention policy be updated to reflect this.
3.	R4	At the time of audit, the establishment had not performed any transplants and patient records were not reviewed; however, the establishment is advised that the discharge letter sent to the donor's medical practitioner should state that, if the donor experiences any serious adverse event or adverse reaction following donation, for example the development of a malignancy, then the establishment must be notified within 24 hours of discovery.
4.	TC1	The surgical lead is responsible for completing HTA A and B forms to NHSBT, the establishment is advised to update documents to reflect that the lead surgeon is responsible for returning HTA A and B forms to NHSBT within seven days"

Concluding comments
The establishment has yet to commence its organ donation and transplantation programme. The surgical team are very experienced in the field of kidney transplantation and have close ties with collaborating pathology laboratories and referral centres.
The establishment has adapted the NOPs into one working SOP which is easy to follow.

Some assessment criteria were not assessed as transplants have not yet taken place.
The HTA has given advice to the establishment with respect to documentation. Prior to commencing transplantation the establishment has been advised to review their SOP on organ donation and transplantation in light of advice and guidance provided during the HTA audit.

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 shortfalls identified during the audit and subject to completion of the existing action plan.

Report sent for factual accuracy: 15 October 2013

Report returned with comments: 18 October 2013

Final report issued: 18 October 2013

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: 6 November 2013

Appendix: Classification of the level of shortfall

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

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to the quality of an organ intended for transplantation or which poses a significant direct risk of causing harm to a donor or recipient.
Or
A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall.
A shortfall in the carrying out of licensable activities which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient
or
A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient;
or
A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;
or
A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting quality and safety of an organ intended for transplantation or the safety of a donor or recipient;

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

3. Minor shortfall:

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

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

Follow up actions

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

- a follow-up audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit audit.

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