Site visit audit report on compliance with HTA requirements

London Bridge Hospital

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

9 April 2013

Summary of Audit findings

London Bridge Hospital (the establishment) was found to have met all assessment criteria.

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

The HTA's regulatory requirements

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

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

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

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

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

Licensable activities carried out by the establishment – Procurement activities

Organ type	
Kidney,	**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 – Transplant 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

The establishment has a living kidney donor programme. It completes around two or three kidney transplants a year. Donor and recipient pairs are generally from overseas. They are either referred directly to the establishment or through their foreign embassies. Patients are assessed onsite by a Consultant Nephrologist and Transplant Surgeon with Practising Privileges at the establishment. Authorisation for transplant and mandatory information is verified by the Transplant Surgeon and Transplant Coordinators before the procedure, which takes place in the establishment's theatres. Following the procedure, patients are given a discharge letter by their Nephrologist. Renal Transplants carried out by the team may often be high risk, in that recipients may have had a number of previous transplants, or require complicated preparatory surgery.

The establishment also has a living liver donor programme. A team from another HTA licensed establishment with an active liver programme carries out living liver transplants at the establishment. All members of the team, including a Donor Coordinator, have individual Practising Privileges. The establishment conducts around five to six liver transplants a year.

For all transplant cases, donor and recipient operations are carried out by separate teams in adjacent theatres. Following the donor operation, the organ is transported to the recipient's theatre in an NHS Blood and Transplant (NHSBT) organ transport box.

All patients seen at the establishment are adults. There is potential for patients to be adult donors for a child recipient. In this case the child would be based at another hospital in London, and the donor transplant surgery would take place at the establishment. The establishment has therefore put transport procedures in place to manage this circumstance.

This first, routine site visit included a tour of the premises, document review, and round-table discussions with the establishment's staff. This consisted of separate discussions with the renal and liver transplant teams, including the Medical Director and Renal Physician, Transplant Specialist Nurse, Renal and Transplant Surgeons, Clinical Manager for Theatres and Donor Coordinator.

The establishment had an existing action plan in place issued with its licence. This was reviewed during the audit. Actions were proposed against assessment criteria TP1 – 5 and TC3. To complete the action plan against assessment criteria, the establishment proposed implementing appropriate operating procedures. The establishment has adapted National Operating Procedure (NOP) 003, to suit the establishment's practices. The action plan will be closed.

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. The establishment does not work with organs from deceased donors.	**None**
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. NOP001 has been adapted as LBH.HTA.SOP001, *Donor and organ characterisation, assessment and allocation in living donation and transplantation.* The establishment has also put a *Living Donor Pre-assessment Form* in place to capture all the mandatory data.	**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.	This criterion is fully met. NOP001 has been adapted as LBH.HTA.SOP001, *Donor and organ characterisation, assessment and allocation in living donation and transplantation.* The establishment has also put a *Living Donor Pre-assessment Form* in place. The form captures information in excess of the mandatory data.	**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. There is a Corporate non-Clinical policy, *Retention period and storage of health records.* This confirms that records are scanned and stored indefinitely. Establishment staff also confirmed that records for organ transplants are stored in paper format after scanning. Paper records going back to 1985, including UK Transplant Service forms were seen during the audit.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The establishment uses laboratories with Clinical Pathology Accreditation (CPA).	**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. The establishment has adapted NOP002 as LBH.HTA.SOP002, *Verification of donor identity, consent and organ and donor characterisation in living donation and transplantation.* There is extensive discussion between the Consultant Physician and Transplant Surgeon prior to transplant. Information is collected on the *Living Donor Transplant Coordinator Checklist* to assist with the process.	**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 is fully met. The establishment has a multi-staged consent process. The *Donor agreement and consent form* includes options for non-transplantable organs. There is a Corporate Consent Policy, *General requirements for clinical consent.*	**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 *Materials Management Policy* states that “Materials must ensure that all products received into the hospital carry a CE mark.”	**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. Cleaning and decontamination are carried out by the Central Decontamination Unit (CDU) at the hospital. Validation certificates were seen for the CDU under Directive 93/42/EEC, ISO9001:2008 and ENISO13485:2003/AC:2009. The establishment has adapted NOP004 as LBH.TH.SOP002, *Transport of contaminated reusable medical devices* and LBH.TH.SOP005 *Trolley preparation for surgical intervention.*	**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. The establishment endeavours to follow up its living donors. This includes giving donors a discharge letter, offering a point of contact for donors and reviewing donor notes at the same time as following up recipients. Advice is provided below.	**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 *Materials Management Policy* states that "Materials must ensure that all products received into the hospital carry a CE mark."	**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. Cleaning and decontamination are carried out by the Central Decontamination Unit (CDU) at the hospital. Validation certificates were seen for the CDU under Directive 93/42/EEC, ISO9001:2008 and ENISO13485:2003/AC:2009. The establishment has adapted NOP004 as LBH.TH.SOP002, *Transport of contaminated reusable medical devices* and LBH.TH.SOP005 *Trolley preparation for surgical intervention and surgical asepsis.*	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. The establishment has adapted NOP004 as LBH.HTA.SOP006, *Transfer and storage of donor and organ characterisation information and storage of traceability data.* The Donor Coordinators ensure batch numbers are written on the HTA A and B forms and there was evidence seen on a renal transplant form. As a back-up, the establishment keeps an organ perfusion fluid and drugs record.	**None**

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 criterion is fully met. The establishment has adapted NOP003 as LBH.TH.SOP003/4, *Organ transplantation, theatre management.* The establishment uses an organ safety checklist to show release from the donor theatre to the recipient, and destination in the unlikely event an organ is not transplanted. The form is completed by the Living Donor Coordinator and circulating practitioner prior to any packaged organ leaving the theatre. If an organ was involved in an external transfer, this form would also be signed by the Consultant Transplant Surgeon.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment has adapted NOP003 as LBH.TH.SOP003/4, *Organ transplantation, theatre management.* The establishment uses NHSBT organ boxes to transfer organs between theatres. It plans to acquire new organ boxes as new validated boxes become available.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled 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 criterion is fully met. The establishment has adapted NOP003 as LBH.TH.SOP003/4, *Organ transplantation, theatre management.*	**None**
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 criterion is fully met. The establishment has adapted NOP003 as LBH.TH.SOP003/4, *Organ transplantation, theatre management.*	**None**

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 criterion is fully met. The establishment has adapted NOP003 as LBH.TH.SOP003/4, *Organ transplantation, theatre management.* The establishment has a service level agreement (SLA) in place with a transport company for the provision of products and associated commercial services. The agreement requires reporting of any adverse incidents immediately to the establishment.	**None**

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. The establishment has adapted NOP002 as LBH.HTA.SOP002, *Verification of donor identity, consent and organ and donor characterisation in living donation and transplantation.* Transplant Surgeons also use the World Health Organization (WHO) surgical safety checklist before implanting the organ.	**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 is fully met. The establishment has adapted NOP002 as LBH.HTA.SOP002, *Verification of donor identity, consent and organ and donor characterisation in living donation and transplantation.* The establishment has adapted NOP003 as LBH.TH.SOP003/4, *Organ transplantation, theatre management.* Transplant Surgeons also use a surgical safety checklist before implanting the organ.	**None**
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. Reference is made to I2.	**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 has adapted NOP006 as LBH.HTA.SOP006, *Transfer and storage of donor and organ characterisation information and storage of traceability data.*	**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. The establishment uses a seven digit "X" number and date of birth to identify donors and recipients.	**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.	This criterion is fully met. The establishment has adapted NOP003 as LBH.TH.SOP003/4, *Organ transplantation, theatre management.* The establishment has not yet had to record the date and time of transportation of organs arriving or leaving the establishment since implementation of the Quality and Safety (Organs) Regulations, but may need to do this in the future.	**None**

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 has adopted NHSBT SOP3888/1, *Reporting an organ donation or transplantation incident to NHSBT as* LBH.HTA.SOP007. Incidents at the establishment are reported through the establishment's electronic reporting system and cascaded to the relevant people depending on the category of incident.	**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.	This criterion is fully met. The establishment has adopted NHSBT SOP3888/1, *Reporting an organ donation or transplantation incident to NHSBT as* LBH.HTA.SOP007.	**None**

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. The SLA with the transport company requires immediate reporting of serious adverse events. The establishment uses its own CPA-accredited laboratories and these report incidents through the establishment's electronic reporting system. It has an SLA in place with an external laboratory and requires reporting of incidents.	**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. There is an education and training programme in place for nurses. All healthcare professionals, not directly employed by the establishment, including Consultants and Nurses are vetted through a formal Practising Privileges process. Healthcare professionals are to work according to the terms and conditions of the establishment's Practising Privileges Policy, LL.UK.100. The process involves personal submission of a complete application form, followed by an interview by the Chief Executive, confidential references and approval by a Medical Advisory Committee.	**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.	This criterion is fully met. All theatre staff, regardless of involvement with transplant surgery have access to a *Self-directed learning package for London Bridge Hospital Theatre Staff*. This includes competency testing and is provided to all new starters in theatre. All new starters are also given observational training on pre and post-transplant educational sessions with patients.	**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. The establishment has adapted NOP005 as LBH.HTA.SOP005, *Activities to be performed under the guidance of a registered medical practitioner in living donation and transplantation.*	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	R4	The establishment makes endeavours to follow-up its donors after transplants in a number of ways. In the unlikely event that a donor organ is not able to be implanted into the intended recipient, a donor may choose the option to offer the organ for allocation into the national pool. In such situations identification of reactions in the donor, that had a potential consequence for the recipient, would be harder to trace without strong follow-up procedures. The establishment is advised to review its discharge letter and ensure the references to reporting serious adverse reactions are clearly articulated.

Concluding comments

There were a number of areas of good practice observed during the audit.

The establishment had adapted the NOPs to suit its own practices. These procedures are supported by documents such as the *Living donor pre-assessment form*, to ensure full capture of mandatory data and *Living donor checklists*, to maintain the integrity of the organ through the organ pathway.

The establishment has a robust consent process in place to maintain an ethical service. This includes tissue-typing for liver transplants to confirm familial relationships and requiring photographic evidence of relationships.

It was easy to see traceability of organs between donors and recipients. The establishment has been using HTA A and B forms well before the implementation of the Quality and Safety (Organs) Regulations.

Theatre staff have access to a learning package, regardless of their level of involvement with transplant surgery. This type of measure improves communication about HTA requirements across the establishment and demonstrates the establishment's commitment to compliance.

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

Report sent for factual accuracy: 31 May 2013

Report returned with comments: 6 June 2013

Final report issued: 10 June 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.