Site visit audit report on compliance with HTA requirements

Barts Health NHS Trust

HTA licensing number 40052

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

30 January 2013

Summary of Audit findings

The Barts Health NHS Trust (the establishment) was found to have met the majority of the applicable assessment criteria. One minor shortfall was found in relation to recording, on the HTA B form, the details of fluids used for organ re-perfusion. The establishment addressed a second minor shortfall, in relation to the return of HTA B forms to NHSBT, to the HTA's satisfaction on the day of the audit. The HTA has provided some advice to further improve practices.

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, R, P, T**
Adult deceased	**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
Adult	**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

The Barts Health NHS Trust is a single-organ centre. All kidney transplantation activity, and donor and organ characterisation tests, other than those undertaken by NHSBT for deceased donors before they are offered, are performed at the Royal London Hospital site in Whitechapel. Barts Health NHS Trust does not provide services to the National Organ Retrieval Service (NORS). Approximately 120 transplants are performed each year, with approximately 60 % of implanted kidneys coming from deceased donors and approximately 40 % from living, directed, donors. Transplantation involves adult patients only; there is no paediatric service.

An action plan was issued to the establishment with its continuous licence in December 2012, due to the lack of a documented procedure for reporting serious adverse events and reactions to NHS Blood and Transplant (NHSBT) (assessment criteria S2, S3). Evidence was presented during the audit to confirm this action had been completed.

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.	The establishment is not responsible for obtaining information relating to a deceased donor. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**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 mandatory donor and organ characterisation information for living donors is collected during work up according to the 'Living Donor Pathway'. Any additional histopathological examination performed on deceased donor kidneys is carried out within the Trust. *The HTA has given advice against this criterion*	**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. Refer to criterion CT2. *The HTA has given advice against this criterion*	**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. The Trust record retention policy states that transplantation records are kept for thirty years.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The accreditation status of the Trust's Histopathology and Clinical Transplantation (which performs histocompatibilty and immunogenetics – H&I – testing) laboratories was confirmed with the CPA's website following the audit.	**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. For deceased donor kidney transplants, the implanting surgeon will speak by telephone with NHSBT Duty Office directly to obtain donor and organ characterisation information, before making a decision on whether to accept the offer of an organ. Surgeons access NHSBT's Electronic Offering System (EOS) in order to confirm organ and donor characterisation. For live donor kidney transplants, donor and organ characterisation information is collected according to the 'Living Donor Pathway'. The implanting surgeon attends the procurement to receive the explanted kidney. *The HTA has given advice against this criterion*	**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. Living donor co-ordinators provide consent information to potential donors and arrange for medical screening. Consent is sought by clinicians during the Living Donor Pathway.	**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 Trust procurement policy addresses this criterion.	**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. Reusable instruments are sterilised at an onsite facility, which is operated by an external company.	**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. Donors attend a follow-up clinic one week after donation, then at six weeks and, subsequently, receive annual health checks. Follow-up data is recorded in the Transplant Database. *The HTA has given advice against this criterion*	**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. Refer to criterion R2.	**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. Refer to criterion R3.	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is almost met. An audit of donor and recipient notes for a live, directed, donation verified that the manufacturer and batch number of perfusion fluids had been recorded on the HTA A and B forms. Perfusion fluid details had not been recorded on the HTA B form for the recipient of a deceased donor kidney. It was unclear from the recipient's notes whether the organ had been re-perfused prior to implantation, although the auditors understood it was normal practice to do so. The establishment must ensure that if any perfusion fluid is used for re-perfusion of a kidney prior to implantation, then the manufacturer and batch number are recorded on the HTA B form, in accordance with the regulatory requirements.	**Minor**

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 not applicable. In cases such as domino or pooled donations, when kidneys are procured from a living donor and transported to another establishment for implantation, transportation will be undertaken by NHSBT-commissioned couriers. The establishment will use an NHSBT kidney box, which is labelled by staff according to the instructions that come with the box, and the HTA A form is attached.	**N/A**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses Kidney boxes which are used by NHSBT. Refer to criterion TP1.	**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. Refer to criterion TP1. In cases when kidneys are not accepted after they reach the hospital, NHSBT commissioned couriers are responsible for re-labelling the kidney boxes, as the establishment is not made aware of the ultimate destination of the kidneys.	**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. Refer to criterion TP1.	**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 not applicable. Transportation is undertaken by NHSBT-commissioned couriers, who report serious adverse events to NHSBT.	**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. The 'Deceased Donor Kidney Pathway' and the HTA A forms are verified during the World Health Organisation (WHO) pre-operative surgical checklist.	**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 nurse in charge of receiving a kidney transport box from the courier will record the time of receipt of the kidney. The surgical Registrar and implanting surgeon will verify preservation and transport conditions. Staff record this information on the 'Deceased Donor Kidney Pathway' form. *The HTA has given advice against this criterion*	**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. Refer to criterion CT6. A surgeon would usually not accept the offer of an organ if there was incomplete information about a deceased donor.	**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. For living donors, page one of the HTA A form is normally faxed to NHSBT the day after the organ procurement. The date when it is faxed is written on the front page of the form. A copy of the whole HTA A form is sent to NHSBT when the donor is discharged from hospital. The auditors noted that the chart used to record that HTA B forms have been sent to NHSBT did not inform staff that forms must be returned within seven days. The establishment amended the chart on the day of the audit to state clearly on the top the seven-day requirement. The HTA is satisfied this amendment addresses the minor shortfall which would otherwise appear against this criterion. During the traceability audit, it was noted that the HTA A form number was transcribed onto the HTA B form for the recipient of a deceased donor kidney, but that this number had not been transcribed to the HTA B form in the living donor case audited on the day. *The HTA has given advice against this criterion*	**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. Living donors and recipients are identified by name and hospital number on relevant documentation and in the Transplant Database.	**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. Refer to criterion TP1. For living donors, a record of transportation to another centre for implantation would be kept with the donor's notes.	**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. Incidents are reported internally through Datix. The establishment has adopted NHSBT's operating procedure for reporting serious adverse events and reactions.	**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. NHSBT's operating procedure for reporting serious adverse events and reactions has been circulated by e-mail to relevant staff. In practice, a surgeon would notify NHSBT of any adverse event or reaction. *The HTA has given advice against this criterion*	**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. H&I laboratory staff are aware of the 24-hour reporting requirement. Transportation is undertaken by NHSBT-commissioned couriers.	**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. Healthcare personnel are registered with the appropriate professional regulatory bodies, and undertake continuing professional development. New staff in the Transplant Directorate receive a Trust induction and a two-week local induction. Training records for a sample of staff were reviewed. Staff have been notified by e-mail and through team meetings of the new 'Deceased Donor Kidney Pathway' form and the operating procedure for reporting serious adverse events and reactions to NHSBT.	**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. Refer to criterion GN1.	**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. Transplant activity is overseen by consultant-level staff.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	R4	Some donors will, following donation, return to their country of origin. This could, potentially, make long-term follow-up more difficult. Donors who return to their home country are provided with a donor discharge letter. The HTA advises the establishment to send a copy of the donor discharge letter to the donor's medical practitioner in their country of origin, so they are informed of the operation and post-operative process, and of any concerns arising.
2.	TC1	The HTA advises the establishment that, in line with the system in place for deceased donor kidneys, the six-digit HTA A form number should be transcribed onto the HTA B form in live donor transplants.
3.	S2	The HTA advises the establishment to upload the procedure for reporting serious adverse events and reactions to NHSBT to the Trust intranet.
4.	CT2, CT3, CT6, I2	The organ pathway forms are used to document key stages in each pathway such as receipt of organs and receipt conditions. The HTA advises the establishment to extend these forms, for example by using flowcharts to document key steps in the transplantation process, identify the responsibilities of key members of staff and reference key documents. This will provide an outline of the overall system and can be used as training materials for new staff and identify key steps for internal audits. The HTA further advises that key documents should be version controlled, with defined review dates. This will help to ensure that staff use only current versions of key documents.

Concluding comments

The strong commitment and professionalism of staff involved with transplantation was very apparent to the auditors. The service is consultant-led, with excellent communication between surgeons, nephrologists and transplant coordinators in the Renal Directorate, and with colleagues in the H&I laboratory. The Trust has two dedicated renal histopathologists, who

are able to carry out histopathological analysis out of hours, if necessary. The H&I laboratory performs a 'bio-ID' to confirm the spleen and lymph node accompanying a deceased donor kidney are from the same individual. The 'Deceased Donor Kidney Pathway' and 'Living Donor Pathway' documents are clear and easy to follow. The establishment uses a comprehensive Transplant Database which is used to record donor and recipient information and tests undertaken following clinical appointments before and after surgery. This database can be accessed remotely from centres in the community, and is used to enter donor and recipient follow up information.

The HTA requires that the establishment addresses the minor 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.

The HTA has given advice to the establishment with respect to some assessment criteria and to quality management.

Report sent for factual accuracy: 21 February 2013

Report returned with comments: 15 March 2013

Final report issued: 18 March 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: 11 April 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.