**Site visit audit report on compliance with HTA requirements**

**BUPA Cromwell Hospital**

**HTA licensing number 40011**

**Licensed for**

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

- **Transplantation Activities: 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**

**4 December 2013**


**Summary of Audit findings**

The HTA carried out an audit of BUPA Cromwell Hospital ('the establishment') focusing on assessment criteria relevant to a new transplantation activity; liver lobe transplantation from living adult donors.

The establishment was found to have met all relevant assessment criteria. It was also verified that minor shortfalls identified at the February 2013 audit had been addressed.

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 reviewed at this audit – Procurement

| Organ type | Liver lobe |
|---|---|
| **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 reviewed at this audit – Transplantation

| Organ type | Liver lobe |
|---|---|
| **Adult** | **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**

BUPA Cromwell Hospital ('the establishment'), a private hospital in London, has been licensed for organ procurement and implantation since August 2012. The establishment currently procures and implants kidneys in living, directed, cases for adult patients. There is no paediatric service. The HTA audited this transplantation activity at the establishment in February 2013; that audit report is available on the HTA's website.

Prior to August 2012, the establishment had also performed liver lobe transplants in living, directed, cases for adult patients. This activity has not taken place since the licensing requirement came into effect. The establishment intends to re-start this programme. The HTA performed a site visit audit in December 2013 to gather information about this activity, and to review documented procedures in place for it. The audit focused on assessment criteria relevant to live liver lobe transplantation only. Criteria relating to retention of donor and organ characterisation information, materials and equipment, and sterilisation of reusable instruments that were assessed as fully met at the February 2013 audit were not re-assessed. The auditors also took the opportunity to verify that minor shortfalls identified at the February 2013 audit had been addressed.

Donors and recipients will typically travel from overseas for this transplant procedure and their immediate post-operative care. Donor and organ characterisation information is gathered at the establishment under the supervision of hepatologists and surgeons from King's College Hospital (HTA licensing number 40023). Surgeons from that hospital will procure, and implant, the liver lobes.

The establishment has developed a unified standard operating procedure (SOP) for its kidney and liver lobe transplantation activities ('SOP001'), based on NHS Blood and Transplant's (NHSBT's) National Operating Procedures. SOP001 covers donor and organ characterisation, consent, procurement and decontamination of materials and equipment, and serious adverse event and adverse reaction (SAEAR) reporting to NHSBT. Advice has been given on making minor amendments to SOP001 (advice item 1).

At the audit, the auditors held round-table discussions with staff who will be involved with this transplantation activity and reviewed documented procedures. As liver lobe transplantation had not commenced, patient notes were not reviewed. A tour of the organ pathway was not considered necessary as procurement and implantation will take place in adjacent operating theatres.

## 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 is not applicable.<br>The establishment does not intend to receive organs from deceased donors at present. | **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.<br>Donor and organ characterisation information specified in Part A of the Annex to the Directive is gathered at the establishment during living donor work-up. It was confirmed that this information includes past or present history of intravenous drug use by the donor. Characterisation information is recorded on the 'Donor work-up checklist'.<br>*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.<br>Where considered appropriate by the clinical team, living donor and organ characterisation 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 was assessed as 'fully met' at the February 2013 audit. | **Not assessed** |
| CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation. | This criterion was assessed as 'fully met' at the February 2013 audit. | **Not assessed** |

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| 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.<br>Retrieval and implantation are to be carried out by different surgeons; the implanting surgeon will enter the donor's operating theatre towards the end of the retrieval procedure and liaises with the retrieving surgeon at that time. | **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.<br>A donor's consent for procurement is 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 was assessed as 'fully met' at the February 2013 audit. | **Not assessed** |
| 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 was assessed as 'fully met' at the February 2013 audit. | **Not assessed** |

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| 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.<br><br>Donors will spend up to ten days recuperating at the establishment following procurement, and then attend the establishment fortnightly to assess the progress of their post-operative recovery. A 'Personal discharge information checklist' is given to every patient. Once a donor is discharged, it is anticipated they will return to the establishment annually for follow-up appointments.<br><br>A minor shortfall against this assessment criterion was identified at the February 2013 audit. The auditors discussed various options for follow-up of kidney, and liver lobe, donors with hospital staff at the December 2013 audit. One option raised by hospital staff, which could enable the establishment to be informed promptly of a potential SAEAR affecting a kidney or a liver lobe donor, was for the embassy which sponsors the donor's follow-up appointments to inform the establishment of a possible SAEAR when the donor returns to their country of origin. The auditors also recognised that, due to the close familial relationship of the donor and recipient, it would be unlikely for the recipient to be unaware of the development of a transmissible infection or malignancy in the donor. Also, donors will be advised by the consultant surgeon during work-up of possible post-transplant co-morbidities. The auditors were sufficiently assured this criterion was being met.<br><br>*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 was assessed as 'fully met' at the February 2013 audit. | **Not assessed** |

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| 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 was assessed as 'fully met' at the February 2013 audit. | **Not assessed** |
| 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.<br>The requirement to record the manufacturer, batch number and expiry date of organ perfusion fluids is described in SOP001. | **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 not applicable.<br>The establishment does not transport organs. In the unlikely event that an organ cannot be transplanted into the intended recipient, contingencies for packaging in preparation for transportation to another centre for implantation are set out in SOP001.<br>*The HTA has given advice against this criterion* | **N/A** |
| TP2) The organ shipping container is suitable for transport of the specified organ. | This criterion is not applicable.<br>*Refer to assessment criterion TP1.* | **N/A** |
| 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 not applicable.<br>*Refer to assessment criterion TP1.* | **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 criterion is not applicable.<br>*Refer to assessment criterion TP1.* | **N/A** |

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| 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.<br>*Refer to assessment criterion TP1.* | **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.<br>SOP001 states that, on the day of surgery, the surgeon will confirm the results of relevant diagnostic tests for the donor. | **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 not applicable.<br>The establishment does not receive organs from other centres. | **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.<br>Donor and organ characterisation information specified in Annex A of the Directive would be collected routinely during donor work-up. Any testing conducted overseas to assess a donor's potential suitability, prior to their arrival into the UK, would be repeated by the establishment. | **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.<br>SOP001 states the requirement and procedure for returning HTA A and B forms to NHSBT within seven days of transplantation.<br>A minor shortfall against this assessment criterion identified in February 2013 was assessed as being met, based on documentation reviewed at this audit. | **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 was assessed as 'fully met' at the February 2013 audit. | **Not assessed** |
| 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 not applicable.<br>The establishment does not transport organs. | **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.<br>Clinical incidents are reported internally through the establishment's Datix system. SOP001 describes the requirement, and procedure, for reporting a potential SAEAR to NHSBT within 24 hours of its discovery.<br>A minor shortfall against this assessment criterion identified in February 2013 was assessed as being met, based on documentation reviewed at this audit.<br>*The HTA has given advice against this criterion* | **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.<br>*Refer to assessment criteria S1.* | **None** |

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| 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.<br>The onsite testing laboratory has been instructed to report a SAEAR to the person who requested the test, and it may also make a SAEAR notification directly to NHSBT.<br>A minor shortfall against this assessment criterion identified in February 2013 was assessed as being met, based on documentation reviewed at this audit. | **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.<br>All transplantation activity takes place under the direct supervision of surgeons and hepatologists from King's College Hospital (HTA licensing number 40023). Staff at the establishment are to receive specific training on liver lobe transplantation during 2014. | **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.<br>*Refer to assessment 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.<br>*Refer to assessment criterion GN1.* | **None** |

### Advice

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

| **No.** | **Assessment Criterion** | **Advice** |
|---|---|---|
| 1. | CT2 | The HTA advises the establishment to clarify in SOP001 whether organ-specific versions of the 'Donor work-up checklist' will be used to collect donor and organ characterisation information, or if the same checklist will be used for kidney and for liver lobe donors. |
| 2. | TP1, S2 | The HTA advises the establishment to review SOP001 prior to commencing |

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| | | living liver lobe transplantation to ensure that any procedural differences between kidney and liver lobe transplants are highlighted. The HTA further advises in relation to this SOP:<br>• in the unlikely event that an kidney or liver lobe cannot be transplanted into the intended recipient, and the donor has consented for re-allocation into the national pool, the establishment should contact NHSBT Duty Office to run a matching algorithm prior to making any arrangements to package the organ for transportation. The establishment can note that current practice is for an organ to be triple-bagged in preparation for its transportation, rather than double-bagged, as stated in the SOP;<br>• SOP001 refers to NHSBT's SOP3888/1 for SAEARs reporting. This was superseded by version SOP3888/2 in November 2013;<br>• SOP001 refers to an 'Appendix Four', but this SOP does not have such an appendix.<br>Two different flowcharts describing how to notify NHSBT of a potential SAEAR were seen at the audit. The establishment should ensure any obsolete versions of this flowchart are removed from circulation. |
| 3. | R4 | For those donors from overseas, one option cited by hospital staff for long-term follow-up was for the embassy to inform the establishment of a possible SAEAR involving the donor once they return to their country of origin. The auditors considered this option to be feasible. The HTA advises that, if this option is adopted, then embassies should receive clear instruction to notify the establishment if the donor experiences an adverse effect which may have arisen from the donation process, or develops a transmissible infection or malignancy, which might potentially have an impact upon the recipient's health. |

**Concluding comments**

The establishment has met all assessment criteria that were assessed at this site visit audit. Also, all of the minor shortfalls identified at the February 2013 were assessed as being met, based on evidence reviewed at this audit. The establishment has, through its previous programme of living liver lobe transplantation, developed a strong working relationship with staff at King's College Hospital.

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

**Report sent for factual accuracy: 06 January 2014**

**Report returned with comments: 21 January 2014**

**Final report issued: 21 January 2014**

## 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.