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

**Royal Brompton and Harefield NHS Foundation Trust**

**HTA licensing number 40019**

**Licensed for**

- **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)**

- **Transplantation Activities: 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**

**18 April 2013**

## Summary of Audit findings

Although the HTA found that Royal Brompton and Harefield NHS Foundation Trust (the establishment) had met the majority of the assessment criteria, a minor shortfall was found, in relation to the traceability assessment criterion, TC1. A shortfall was identified as the establishment does not have a sufficiently detailed documented operating procedure covering the completion and return of HTA A and B forms.

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 | Heart | Lung |
|---|---|---|
| **Adult** | **DC, OC, P, T, R** | **DC, OC, 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 | Heart | Lung |
|---|---|---|
| **Adult** | **OC, P, T, I** | **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 Royal Brompton and Harefield NHS Foundation Trust (the establishment) carries out both heart and lung transplants in adult patients. All transplant surgery takes place at the Harefield hospital site.

The establishment also provides staff to the cardiothoracic National Organ Retrieval Service (NORS) teams.

Tissue typing and cross matching are performed at the establishment's laboratory also located at the Harefield hospital site. Other additional characterisation tests such as additional histopathological tests are performed by the establishment's pathology laboratory.

Transportation of organs is carried out by a specialist courier company under an agreement with the establishment or by an NHSBT commissioned courier.

**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. | The establishment does not currently have a living donor program. | **N/A** |
| 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><br>Additional characterisation tests on organs from deceased donors would normally be carried out at the retrieval hospitals however, the establishment does have access to histopathological services within their own laboratories which could undertake any further test upon arrival of the organ. | **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.<br><br>The Trust's clinical records management policy states that records relating to transplantation will be kept for 30 years. Additionally, the SOP on retention and destruction of records confirms that donor and transplantation records will be kept for 30 years. | **None** |

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| CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation. | This criterion is fully met.<br><br>The establishment's laboratories used for tissue typing have current CPA and EFI accreditation. The current CPA and EFI certification certificate was reviewed during the audit. | **None** |

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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><br>The on-call recipient coordinator receives a phone call from NHSBT when an organ from a deceased donor is offered. The recipient coordinator collects the donor identification number and logs onto the Electronic Offering System (EOS) to collect further data about the donor including information on donor characterisation. Data from EOS is recorded on a Donor Referral form.<br><br>Once donor information has been collected both verbally from the SNOD and electronically from EOS, donor information is passed verbally to the on call transplant fellow or surgeon so they can make a decision to accept the organ or not. Additionally, the transplant fellow or surgeon also have access to EOS should they wish to review more up to date information. This verbal communication is recorded on the donor referral from.<br><br>If accepted the recipient coordinator and transplanting surgeon review the recipient waiting list to shortlist potentially suitable recipients. There is continuing communication between the recipient coordinator at the establishment and the SNOD at the donor site to update further medical information as it becomes available. Laboratory staff are also involved and carry out virtual cross match checks against the recipient waiting list. Records of virtual cross matches are filed in the recipient patient's medical records.<br><br>The implanting surgeon reviews all donor characterisation and medical information prior to scrubbing into theatre. Due to the ischemic time constraints of hearts and lungs if the organ was unsuitable for any reason upon receipt by the establishment it is not envisaged that they would ever be offered back into the donor pool.<br><br>The establishment has adopted National Operating Procedure one (NOP1) which sets out the responsibility of the retrieving surgeon. Additionally NOP1 details some extra organ characterisation tests that may be carried out. Although the establishment has adopted NOP1 and amended some aspects of the procedure to reflect local practice, NOP1 is not sufficiently detailed to reflect all aspects of the retrieval procedure. For example, a Trans-bronchial bronchoscopy is carried out in all lung retrievals however this additional test is not listed in the NOP document. Advice is given below. | **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><br>Consent is sought by a SNOD working under NHSBT's licence. Prior to retrieval by the establishment's National Organ Retrieval Service team (NORS) the consent documentation is checked by the retrieving surgeon and is additionally checked in the operating theatre as part of the World Health Organisation (WHO) surgical check list. | **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.<br><br>The establishment has confirmed that the Trust only purchase equipment that complies with the Medical Devices Regulations 2002 and there is a draft policy to this effect being produced however this was not reviewed as part of the Audit. A Trust level document on the on-going lifecycle management of medical devices in order to comply with the Medical Devices Regulations was however reviewed.<br><br>The establishment also uses equipment for performing ex-vivo lung perfusion and also normothermic organ perfusion equipment for both transport and preservation of hearts and lungs. All equipment used for these purposes is CE marked. | **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.<br><br>Instruments used during organ retrieval are sterilised by the establishment's sterile services department. The accreditation certificate was reviewed during the audit. | **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 not applicable.<br><br>The establishment does not currently have a living donor program. | **N/A** |

| 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.<br><br>Reference is made to 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.<br><br>Reference is made to 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 fully met.<br><br>Details of perfusion fluids are recorded on the appropriate HTA A and B forms which are returned to NHSBT.<br>An audit of recipient patient medical notes and associated HTA A and B forms demonstrated that perfusion fluids were being recorded as required.<br><br>The establishment also uses the normothermic organ perfusion equipment for transport and preservation of hearts and lungs. This system is new and being used as part of two clinical trials. Currently, only two centres in the UK use the normothermic organ perfusion equipment. When using the normothermic organ perfusion equipment a number of units of perfusion fluid is used and there is insufficient room on the appropriate HTA A and B to record all of the perfusates.<br><br>Advice has been given below to the establishment regarding the recording of this perfusion fluid. | **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.<br><br>Hearts and lungs are transported in proprietary cool boxes. The establishment will switch to using the approved NHSBT transport boxes as soon as these become available nationally.<br><br>The establishment has adopted NOP3 which when used in conjunction with the clinical guide 'Donor Retrieval Protocol' gives detail on how to appropriately pack organs for transport.<br><br>The establishment seals the cool boxes used for transport with tape and also use a system of address labels to indicate that a box contains an organ or is awaiting an organ in addition to detailing the destination of the organ.<br><br>The method of sealing and use of the labeling system however is not currently reflected in NOP3.<br><br>Advice has been given below regarding the amendment of NOP3. | **None** |
| TP2) The organ shipping container is suitable for transport of the specified organ. | This criterion is fully met.<br><br>Refer to 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.<br><br>Refer to TP1. | **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.<br><br>Refer to CT6. | **None** |

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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 fully met.<br><br>The establishment has a contract with a courier company that is widely used for transporting organs. The establishment indicated that the courier has been notified of the requirements for serious adverse event reporting. Additionally the courier company has a code of conduct that would be followed by its drivers. This code of conduct that was reviewed during the audit stipulates that any adverse incidents must be reported to both the courier company and 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.<br><br>The establishment has adopted NOP2 which covers implantation of organs. The establishment uses a 'Surgical Safety Checklist' which is reviewed prior to the implantation commencing. Part of this process is to update the surgeon on any additional information that they may need prior to commencing with the surgery. Additionally, the transplant coordinator indicated that the surgeon reviews all relevant paperwork prior to scrubbing into theatres. This includes information from the relevant HTA A and B forms, a hard copy of the donor offer form, laboratory test results and a print out from EOS. | **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.<br><br>The implanting surgeon and transplant coordinator verify the condition of the organ upon arrival at the establishment. | **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.<br><br>Where any required donor information is not available the implanting surgeon will make a risk-benefit analysis and document this in the recipient's clinical 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 not met.<br><br>The establishment has adopted NOP6 and has made some amendments to adapt it for use at the establishment. The document, however, remains too generic and does not specify who has responsibility for completing and returning A and B forms. | **Minor** |
| 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.<br><br>The deceased's organs are identified using the donor identification number. This number links to the donor records in EOS and is additionally recorded on the HTA A and B forms. | **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.<br><br>Transportation records form part of the transplant record maintained by the establishment. | **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.<br><br>The establishment has developed an in-house version of the SAEARs reporting procedure to reflect the process that is followed at the establishment which includes use of the internal Datix system in addition to the NHSBT adverse event reporting system. The procedure includes detail of who will report, investigate and within what timeframe incidents need to be reported. | **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><br>Refer to S1 | **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.<br><br>The establishment indicated that the courier company's drivers have been informed about the requirement to report SAEARs to the establishment. | **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><br>The establishment has a system of competency based training in place. | **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 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><br>The establishment's activity is overseen by consultant level staff. The establishment has adopted NOP5 which sets out how activities are overseen by registered medical professionals. | **None** |

### Advice

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

| No. | Assessment Criterion | Advice |
|---|---|---|
| 1. | CT6 | Although the establishment has adopted NOP1 and amended some aspects of the procedure to reflect local practice, NOP1 is not sufficiently detailed to reflect all aspects of the retrieval procedure. For example, a Trans-bronchial bronchoscopy is carried out in all lung retrievals however this additional test is not listed in the NOP document.<br><br>The establishment is advised to review NOP1 and make further adaptations so that the procedure correctly describes all local procedures and practices. |
| 2. | P3 | When using the normothermic organ perfusion equipment a number of units of perfusion fluid is used and there is not sufficient room on the appropriate HTA A and B to record all of the perfusates.<br><br>The establishment is advised to develop a system by which details of the extra perfusion fluids used when transporting and preserving an organ when using the normothermic organ perfusion equipment can be returned to NHSBT with the HTA A and B forms. The establishment may wish to consider contacting NHSBT regarding a suitable format for the extra information to be provided if it cannot be accommodated on the usual HTA A and B forms. |
| 3. | TP1 | The establishment has adopted NOP3 which when used in conjunction with the clinical guide 'Donor Retrieval Protocol' gives detail on how to appropriately pack organs for transport.<br><br>Although the establishment has adopted NOP3 and amended some aspects of the procedure to reflect local practice, NOP3 is not sufficiently detailed to reflect all aspects of the retrieval procedure. For example, the method of |

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|---|---|---|
| | | sealing and use of the labeling system is not currently reflected in NOP3.<br>The establishment is advised to review NOP3 and make further adaptations so that the procedure correctly describes all local procedures and practices. |
| 4. | General | The establishment has adopted all of the NOPs and made some adaptations removing information that is not applicable or reflects local practice. By using additional documents and procedures, such as the Surgical safety Checklist the establishment has been deemed to meet the majority of the assessment criteria. However, although the use of additional documents supports the NOPs the establishment is advised to undertake a review of all adopted NOPs and where appropriate, amend them to more closely reflect local practice. |
| 5. | General | During the inspection the establishment indicated that it may wish to develop a living lung donor program in the future.<br>Should a living donor program be developed in the future the establishment is advised that the following assessment criteria and any associated procedures will require reviewing in light of the new activity. Additionally, procedural documents will require revision or new procedural documents developing to cover the living donor program activity :-<br>CT1, CT3, CT4, CT5, CT6, R1, R2, R3, R4, P!, P2, P3, I1, I, I3, TC1, TC2, TC3<br>Should the retrieved organ require transport to another establishment TP1 to TP5 should also be reviewed to assure the establishment that procedures remain suitable. |

**Concluding comments**

Despite the minor shortfall areas of strength and good practice were identified during the audit.

The competence training program for transplant coordinators is detailed and helps to assure the establishment that staff are fully trained and competent before undertaking transplant related activities.

There is an area of practice that requires improvement, one minor shortfall. Additionally advice has been given to the establishment with respect to various procedural documents.

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.

**Report sent for factual accuracy: 22 May 2013**

**Report returned with comments: 6 June 2013**

**Final report issued: 20 June 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: 30 September 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.