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 as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014

13 June 2019

Summary of Audit findings

Royal Brompton and Harefield NHS Foundation Trust (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to temperature monitoring and procedural documentation.

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

Royal Brompton and Harefield NHS Foundation Trust has been licensed by the HTA since December 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. The establishment undertakes heart and lung transplants in adult patients. In addition, the establishment participates in the national organ retrieval service (NORS) through which it retrieves hearts and lungs from adult donors.

Perfusion fluid and other solutions used during retrieval and transplantation are stored in two dedicated storage areas at the hospital site. The main stock of perfusion fluids and other solutions are stored in a dedicated storeroom near to the establishment's theatres. Both the ambient temperature of the room and the temperature of the storage fridge are monitored using a maximum/minimum thermometer. A smaller stock of perfusion fluid, including fluid used during mechanical normothermic perfusion of hearts, is stored within the establishment's theatres. Again, a chilled and ambient stock of solutions are stored at this location. Advice has been given below regarding the temperature monitoring of the solutions stored within theatres.

The establishment has adopted National Operating Procedure 004 (NOP004), which stipulates that all equipment must meet the requirements of the medical devices regulations. To supplement NOP004, the establishment's Trust's medical devices policy also stipulates that only equipment that meets the requirements of the medical devices regulations and is CE marked may be purchased. NOP004 also sets out the requirement that all equipment used in transplant and retrievals is subject to suitable sterilisation procedures. The establishment uses some equipment that cannot be sterilised in the usual manner such as bronchoscopes and trans-oesophageal echocardiogram (TOE) probes. These devices are subject to separate cleaning and sterilisation procedures after each use. During the audit, accreditation certificates relating to the establishment's sterile services provider, and the re-processing of bronchoscopes, were reviewed and these demonstrated that the necessary requirements were met and were in date.

All of the laboratories used by the establishment to undertake donor characterisation assessments have appropriate accreditation from the relevant accreditation body. Records relating to the Histocompatibility and Immunogenetics (H&I) laboratory, the histopathology laboratory and the virology laboratory used by the establishment were reviewed. The H&I laboratory has both current United Kingdom Accreditation Service (UKAS) accreditation and European Federation of Immunogenetics (EFI) accreditation in place.

The establishment has various training packages and competency assessments for establishment staff undertaking transplant and retrieval related activities. The core transplant team is made up of consultants. Junior transplant fellows may undertake surgical activity during which they are supervised by a certified NORS surgeon. New surgical staff observe procedures in the first instance and then work under supervision until deemed competent to work independently. All retrieval surgeons attend the retrieval masterclass training course. Theatre staff use the national organ retrieval competencies for training. Transplant coordinators have the same competencies as nursing staff with the addition of some coordination specific competencies. New transplant coordinators are supernumerary when commencing their training so they are able to observe and be supported while learning. Working continues with supervision until the transplant coordinator is deemed competent to work independently. Some staff have received training in the use of the normothermic mechanical perfusion equipment from the equipment's manufacturer and are able to cascade this learning to other establishment staff. Training in mechanical perfusion however can only be cascaded to others by those who received their training directly from the manufacturer.

Heart and Lung Transplantation

Recipient coordinators (RC) receive notification of an organ offer from NHSBT's Hub via a pager through which they receive three donor identifiers, and recipient details if the offer is for a named recipient. The RC logs into the Electronic Offering System (EOS) in order to access the donor and organ characterisation information. The organ offer is discussed with the transplant surgeon with details of all conversations recorded by the RC. The RC liaises with the H&I laboratory and, provided that the surgeon assessed the offer as suitable and the organ is a suitable match for the recipient, accepts the offer.

The RC liaises with the specialist nurse for organ donation (SNOD) at the donor centre so that they are aware of any update regarding the offer. In the case of heart transplants, the establishment always sends a small retrieval team, even if they are not the retrieving NORS team. This small team takes along the equipment needed for mechanical normothermic perfusion. The establishment normothermically perfuses all donor hearts that it transplants using a mechanical perfusion device. If the establishment is not providing a NORS team during a retrieval, this smaller two-person team attends the retrieval centre and aims to arrive at the same time as the allocated NORS team. The establishment's team retrieves hearts from DCD donors however; the attending NORS team would retrieve from DBD and pass the retrieved heart to the establishment's team in preparation for mechanical perfusion. The establishment downloads all organ characterisation data generated from the mechanical perfusion device and stores this on the Trust's server.

The establishment receives characterisation information such as bronchoscopy results and cardiac assessments via the RC who passes the information to the implanting surgeon. If there are any increased risks posed to the recipient associated with a donor organ, the implanting surgeon discusses these with the recipient prior to surgery and records these conversations in the recipient's clinical notes. Upon arrival of the organ at the establishment, a transplant fellow checks the accompanying paper work and donor/organ information, which is then re-checked by the implanting surgeon prior to implantation. The establishment may mechanically perfuse lungs ex-vivo (EVLP) in order to asses their function if the implanting surgeon deems it necessary. Around 10% of donor lungs undergo EVLP characterisation assessment. Upon completion of the transplant, the implanting surgeon completes the HTA-B form, which is returned to NHSBT by the RC. The establishment is now using an electronic HTA-B form and advice and guidance has been given below in relation to this.

National Organ Retrieval Service (NORS)

The establishment's NORS team is mobilised by the transplant coordinator following a call from the NHSBT Hub. Theatre staff collect the required solutions, ice and instruments and the NORS team is contacted. Some instruments and equipment are pre-packed in boxes ready to be deployed along with the NORS team; checklists are in place for establishment staff to follow when packing such retrieval kits.

Upon arrival at the retrieval site, the lead surgeon contacts the SNOD. Theatre staff prepare the equipment and once ready, there is a hand over with the SNOD. The whole retrieval team is involved in the hand over. The retrieving surgeon reviews the donor blood group, consent form, any neurological testing results, investigations carried out on the donor and any images such as computerised tomography (CT) and X-ray.

The retrieval team liaises with the SNOD with regards to any suspicious lesions identified during retrieval. Histological analysis may be organised at the retrieval centre or one of the NORS teams may take the samples for analysis. The presence of any lesions and the results of investigations into them are communicated to all recipient centres by the SNOD. If the establishment is also the recipient centre for the heart, the organ will be mechanically perfused following retrieval and during transit back to the establishment. The establishment is also part of the DCD heart retrieval/transplant programme and may retrieve hearts from DCD

donors. Upon completion of the organ retrieval, the retrieving surgeon completes the HTA-A form.

Audit of Clinical Notes

Audits of clinical notes relating to donation and transplant were reviewed during the audit and included notes relating to one heart recipient and one lung recipient. During the review, copies of EOS, the HTA-A and HTA-B forms, the RC's contemporaneous notes and the establishment's form used to capture all transplant related timings were reviewed. Details of perfusion fluids used were recorded on the HTA forms as expected. The establishment completes the HTA-B form electronically. Electronic data relating to the two transplants were also reviewed during the audit.

Compliance with HTA assessment criteria

All relevant assessment criteria were assessed as being met.

Advice

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

No.	Assessment Criterion	Advice
1.	P3	During the audit, the audit team started a review of temperature records relating to the small stock of perfusion fluids which are held in the establishment's theatres. It was found that the temperature records relating to this area had not been recorded. In addition, investigation into the temperature monitor's alarm settings found that the upper temperature alarm limit was set at 26^{o}C. This is higher than the mechanical perfusion fluid's manufacturer's upper storage temperature limit of 25^{o}C. The establishment is advised to review and adjust the temperature monitor's alarm points so that establishment staff would be alerted to a temperature excursion from the desired range, before it exceeds the manufacturer's storage temperature limits. In addition, the establishment is advised to put in place systems to assure itself that the temperature of the storage room in theatres is recorded as it expects.
2.	TC1	Completion and return to NHSBT of the HTA-B forms is described in the establishments NOP006 document. The establishment is advised to review and update this document so that it reflects the use of electronic HTA-B forms.

Concluding comments

The HTA has given advice to the establishment with respect to temperature monitoring and procedural documentation.

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

Report sent for factual accuracy: 12 July 2019

Report returned with comments: No comments received

Final report issued: 2 August 2019

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.