Site visit audit report on compliance with HTA requirements

Papworth Hospital NHS Foundation Trust

HTA licensing number 40033

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

1 March 2019

Summary of Audit findings

Papworth Hospital NHS Foundation Trust (the establishment) was found to have met all assessment criteria.

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

Particular examples of 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 deceased	**DC, OC, P, T, R**	**DC, OC, P, T, R**
Paediatric deceased	**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 deceased	**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

Papworth Hospital 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 adult heart and lung transplants. In addition, the establishment participates in the national organ retrieval service through which it retrieves hearts and lungs from adult and paediatric donors.

Perfusion fluid and other reagents used during retrieval and transplantation are stored in a dedicated storage area on the hospital site. As fluids are required for use in transplantation surgery, they are moved to theatres just prior to the surgery commencing. Fluids required during retrievals are packed along with other retrieval equipment, which is stored in the same area, while the retrieval team prepares for mobilisation. A stock of fluids is stored within a fridge, which is monitored and the temperature recorded daily during the working week. The temperature probe used for taking the temperature reading shows the temperature of the fridge at the point that the reading is taken. Advice has been given below with regards to considering the use of a temperature probe which records current temperature and in addition, maximum and minimum temperatures (see advice item 3). A larger bulk stock of un-refrigerated fluids and other reagents are also stored at the same site in a secure stock room.

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 the NOP004, the establishment's Trust has a range of policies in place which support the requirements of the medical devices regulations and associated bulletins. NOP004 also sets out the requirement that all equipment used in transplant and retrievals is subject to suitable sterilisation procedures. Equipment that cannot be sterilised with other surgical equipment such as re-usable bronchoscopes and Trans oesophageal echocardiogram (TOE) probes are subject to separate cleaning protocols. Re-usable scopes used during retrievals undergo a clean after use before being returned to the establishment for re-processing. The cleaning and sterilisation of TOE probes is covered by a dedicated standard operating procedure with those undertaking this procedure being subject to competency based training. During the audit accreditation certificates, relating to the establishment's sterile services provider, 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 used by the establishment were reviewed. The H&I laboratory has current United Kingdom Accreditation Service (UKAS) accreditation in place. The UKAS certification records for the laboratory used to undertake virology testing were also reviewed and found to be current.

The establishment has various training packages and competency assessments for the various staff undertaking transplant and retrieval related activities. Transplant coordinators (TC) observe existing staff initially when starting in the team. Over time, they gradually take on more responsibility with a reduction in supervision. Over this period, they are competency assessed before being signed off as competent to work independently. The process of training transplant practitioners is similar with a final sign off once the member of staff is assessed as competent. Donor care physiologists, who undertake many roles during organ retrievals, follow a similar framework however each element of the role has its own training requirements. For example, use and cleaning of TOE probes and bronchoscopes, care of the donor, and use of the normothermic perfusion equipment. Perfusionists at the establishment follow their own training programme and again this starts by observing experienced staff before reducing the amount of supervision and being signed off as fully competent. Surgical staff also undergo competency based training and supervision. Surgical staff involved in

retrievals must undertake ten heart and ten lung retrievals in addition to attending the retrieval master class before being signed off as competent to work independently. Transplant surgeons are mentored and perform procedures with an experienced colleague also being scrubbed in and working alongside them when they start undertaking procedures at the establishment. All staff have access to continuous professional development and annual appraisals.

The establishment is preparing to move to new premises in the near future. Although transplant procedures will not be affected by the move, the HTA has undertaken to revisit the establishment shortly after its move so that the premises may be reviewed.

Heart and Lung Transplantation

Offers are received from the NHSBT Hub by the TC who takes three points of identification relating to the donor before logging into the electronic offering system (EOS) to view the donor and organ characterisation information. High level information is transcribed onto a transplant log, which is also used by the TC to record contemporaneous records of conversations and actions relating to the offer, and other transplant related procedures for example, transport of the organ and expected timings. The TC will aim to receive an echocardiogram and other donor and organ characterisation information from the donor hospital. A donor care physiologist may go to the donor hospital, depending upon its location, and assist in collecting some of this characterisation information prior to the arrival of the retrieval team.

Information about the offer is discussed with the on-call registrar or implanting surgeon who may then also discuss the offer with a colleague. If the offer has not been made for a specific named recipient, the surgeon will then review the establishment's records and discuss potential recipients. If the offer is accepted, the potential recipient is called into the hospital and is met by the TC who takes bloods and prepares them for theatre. During the lead up to retrieval, the TC receives updates on inotrope levels for hearts and blood gases for lungs in addition to other pertinent characterisation information. If necessary, the implanting surgeon may call the retrieving surgeon to discuss aspects of the donor or donor organ directly with them. Any additional risks posed by an organ or donor, even if discussed in general terms at the time the recipient was listed for transplant, are discussed between the implanting surgeon and recipient and are recorded within the recipient's clinical notes. The establishment reviews the recipient's sensitisation status and liaises with the H&I laboratory for advice on the cross match testing requirements between the recipient and donor.

Arrival of the donor organ at the establishment is recorded on the establishment's bespoke perfusion sheet. The TC checks the accompanying paperwork to verify that the details of the donor organ are as expected and match the expected details on EOS. The transport box is opened and the sterile inner bag containing the organ is passed into the surgical field to the implanting surgeon so that they can inspect the organ prior to implantation. Timings such as cold and warm ischaemic times and time of re-perfusion in the recipient are recorded. The implanting surgeon completes the HTA-B form which is returned to NHSBT by the establishment's data team.

National Organ Retrieval Service (NORS)

The establishment's NORS team comprises a lead surgeon, scrub nurse, transplant practitioner, donor care physiologist and sometimes a second surgeon and trainee surgeon. Retrieval kits are made up and stored ready to go upon mobilisation of the retrieval team. Checklists to guide the making up of retrieval kits are in place for all of the various types of retrieval kits used by the establishment. These include equipment relating to heart retrievals following circulatory death and lungs which will undergo normothermic perfusion during transport from the donor site. The TC receives a call to mobilise the retrieval team from NHSBT's Hub and the team will be en-route to the donor hospital within one hour. The

retrieval team contact the specialist nurse for organ donation (SNOD) at the donor centre while in transit to the donor site to discuss the donor and any other relevant information.

Upon arrival the surgeon discusses the donor with the SNOD in relation to the donor details including, the donor's age, cause of death, height, weight, the organs to be retrieved and details of other retrieval teams which will be present. The surgeon reviews the consent form, donor blood group, brain stem death testing results (if applicable), clinical notes and previous medical history. Two ambulances are present, one to transport the heart and one for the lungs. If a heart is being retrieved from a donor following circulatory arrest (DCD), the organ is placed onto a normothermic perfusion device where it will remain during transport to the recipient hospital. The donor care physiologist is responsible for perfusion of organs and the maintenance of the organs while on the normothermic perfusion device. Organs retrieved from donors following brain stem death (DBD) are retrieved and transported in static cold storage on ice. The donor care physiologist also oversees the packing and labelling of the organs. The HTA-A form is completed by the donor care physiologist or transplant practitioner under the supervision of the surgeon who remains scrubbed in to the procedure.

Audit of Clinical Notes

Audits of clinical notes relating to donation and transplant were reviewed during the audit as detailed below:

One set of records from a DCD normothermically perfused donor heart recipient.

One set of records from a single lung transplant recipient.

One set of records from a double lung transplant recipient.

One set of records from a DBD donor heart recipient.

In all of these cases, where applicable, the following records were reviewed: A copy of EOS, HTA-A and HTA-B forms, normothermic functional assessments while the donor heart was on the perfusion device, the transplant log including the contemporaneous records relating to the transplant from offer to implantation and the perfusion sheet which includes details of the organ's arrival at the establishment.

The establishment's documented procedure relating to transplants states that the implanting surgeon will sign the hard copy of EOS prior to the transplant surgery. During the audit, four hard copies of EOS were reviewed however, only one of the four copies had been signed by the implanting surgeon indicating that the establishment is not routinely following its own procedure (see advice item 4).

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.	CT2	The establishment repeats the donor infectious disease marker serological testing on a sample of donor blood arriving with the organ. The establishment is advised to include details of this second test within its documented procedures and also to include the course of action that would be taken if the results of the second test differed from the initial testing information received via EOS.
2.	CT4	Data generated by the normothermic perfusion device used to characterise hearts retrieved from DCD donors is recorded on a log sheet created by the establishment however, data generated during the normothermic perfusion of lungs is saved to the device and transferred to a memory stick. The establishment is advised to document the process of transferring this data for perfused lungs and to document how this data will be stored for thirty years as required by the Regulations. In addition, the establishment may wish to consider downloading the data from the memory stick to the establishment's Trust server.
3.	P3	The establishment monitors the storage temperature of chilled perfusion fluid using a temperature probe which gives the temperature of the perfusion fluid at the time when the reading is taken. The temperature of the bulk stock of perfusion fluid and other reagents, which are stored at ambient temperature, is not monitored. The establishment is advised to consider the use of a maximum and minimum temperature logging device to monitor the temperature of the perfusion fluid and other reagents both in the fridge and in the bulk store room. The regular reviews of the temperature could include the review of the maximum and minimum temperature to which the perfusion fluid has been exposed to since the last temperature reading was taken. This may provide the establishment with the assurance that the perfusion fluids have not been exposed to a temperature outside of the manufacturer's advised storage temperature limits.
4.	I1	The establishment's documented procedure relating to transplants states that the implanting surgeon will sign the hard copy of EOS prior to the transplant surgery commencing. However, during the audit, only one of the four copies reviewed had been signed by the implanting surgeon. The establishment is advised to review its procedure to assess if the process of signing the hard copy form remains appropriate or if the procedure could be modified to increase compliance. For example, and as the establishment suggested during the audit, if the TC could record giving the copy of EOS to the surgeon by signing it themselves.
5.	TC1	The establishment has adopted NOP006 which outlines the process relating to the return of the HTA-B forms to NHSBT. The establishment is advised to update this procedure to reflect that it is the establishment's data team that returns the forms to NHSBT.
6.	GN3	The establishment has adopted NOP005 which outlines which member of the transplant team is responsible for undertaking which transplant related activities. The establishment is advised to update NOP005 to reflect the roles of the donor care physiologist with regards to the activities that they undertake including the use of the normothermic perfusion equipment.

No.	Assessment Criterion	Advice
7.	General	The establishment may wish to consider occasionally inviting a member of staff from the H&I laboratory used by the establishment to one of the establishment's governance meetings. The establishment has a good working relationship with the laboratory and attendance at occasional meetings may help to strengthen the working relationship in addition to keeping both parties up to date with ongoing developments within each other's organisations.

Concluding comments

Areas of good practice were observed during the audit, some examples of these are included below.

- In addition to the checklists of equipment and reagents used when making up retrieval kits, the establishment has developed some specific checklists relating to the normothermic perfusion equipment and associated consumables. In addition to bespoke checklists, once the retrieval kit has been prepared, the container holding the consumables is sealed with a plastic tie to help assure the establishment that the kit remains complete. This helps to assure the establishment that when preparing to leave for a retrieval, all of the necessary equipment is packed and available.

- The establishment cleans the transport boxes after each use and uses 'I am clean' stickers so that establishment staff can assure themselves that only cleaned transport boxes are used when leaving for retrievals. The same 'I am clean' stickers are also used on other equipment, for example, the normothermic perfusion devices. In addition, the establishment also cleans the machine that makes ice which is used during organ retrievals.

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

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

Report sent for factual accuracy: 29 March 2019

Report returned with comments: 12 April 2019

Final report issued: 30 April 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.