Site visit audit report on compliance with HTA requirements

Portsmouth Hospitals NHS Trust

HTA licensing number 40020

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

2 July 2018

Summary of Audit findings

Portsmouth Hospitals NHS Trust (the establishment) was found to have met all assessment criteria.

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

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria:

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.

Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 1: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Licensable activities carried out by the establishment – Procurement activities

Organ type	Kidney
Adult living	**DC, OC, P, T, R**

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)

Licensable activities carried out by the establishment – Transplant activities

Organ type	Kidney
Adult	**OC, P, T, I**

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)

Background to the establishment and description of audit activities undertaken

Portsmouth Hospitals NHS 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 kidney transplants from cadaveric donors. In addition, the establishment has a living donor kidney transplant programme.

The establishment is based at the Queen Alexandra Hospital. Perfusion fluid and saline is stored in fridges within the theatres and although temperatures were monitored, there were some gaps in the temperature monitoring history. In addition, the room in which additional stocks of perfusion fluids were stored were not temperature monitored (see advice below).

Documentation demonstrating that the establishment's sterile services provider met the requirements of the assessment criteria was reviewed during the audit. In addition, 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 systems in place to ensure that all goods which are supplied to the Trust have valid CE marking.

All of the laboratories used by the establishment to undertake donor characterisation assessments have appropriate accreditation from the relevant accreditation body. The Histocompatibility and Immunogenetics (H&I) laboratory has both current Clinical Pathology Accreditation (CPA) and European Federation of Immunogenetics (EFI) accreditation. The blood sciences and biochemistry laboratories, blood sciences department, department of haematology and cellular pathology laboratories all have current United Kingdom Accreditation Service (UKAS) accreditation.

Clinical staff all undergo a period of training when starting work at the establishment. Initially new staff, including nursing and coordinator staff, shadow existing team members. When starting to undertake tasks themselves, new staff are accompanied by an experienced member of staff before working independently. Once working independently, support is always available from on-call colleagues. The establishment hosts regular education days and all staff have annual appraisals.

The establishment has a mentoring policy in place relating to new consultant surgical staff. Log books of new surgical staff are reviewed as part of the induction processes. New surgical staff are observed during their first five transplant procedures by an existing surgical colleague before being signed off to work independently at around three months of them starting work at the establishment.

Cadaveric Donor Kidney Transplantation

The on-call transplant coordinator receives the initial organ offer call from NHSBT's Hub, and records donor details in addition to the name of the Hub staff member that called and the time of the call. The coordinator logs in to the electronic offering system (EOS) and uses the donor details from the call to obtain the donor and organ characterisation information. The characterisation data required by the establishment's implanting surgeons is recorded by the coordinator using a bespoke form. Finally, the coordinator reviews the clinical notes of the potential recipient to review their current condition before calling the on-call surgeon.

The surgeon may request further information which is obtained by the coordinator either via the Hub or through direct contact with the specialist nurse for organ donation (SNOD) at the donor site. The surgeon also discusses the offer with a nephrologist and, if required, can log onto EOS to view all of the donor and organ characterisation information. The surgeon then contacts the coordinator to accept or decline the offer. The coordinator maintains a contemporaneous record of all conversations and their outcomes.

If the offer is accepted, the coordinator calls the intended recipient and asks them to attend the hospital. The coordinator also contacts the H&I laboratory to see if the recipient can proceed to transplant on a virtual cross match or if a wet cross match is required. In cases where recipients proceed to transplant on the basis of a virtual cross match, a wet cross match is always undertaken following the transplant. Receipt of the organ at the establishment is recorded and the ice levels are checked on arrival to confirm that there is sufficient ice in the transport box. The organ transport box is then stored in a locked fridge on the renal ward. Prior to surgery, the surgeon reviews the recipient and collects the organ from the ward and takes it to theatres. Should there be any additional or raised risk associated with the donor or organ, risks and benefits are discussed between the recipient and surgeon and recorded in the clinical notes prior to the transplant surgery.

The completed and signed HTA-B form are collected by the clinical nurse specialist, scanned and returned to NHSBT via secure email. All organ offers that are declined by the establishment are reviewed and if the organ went on to be transplanted elsewhere, the recipient's progress is followed up post transplant. This helps the establishment in assuring itself that its acceptance and rejection criteria continue to remain appropriate.

Living Kidney Donor Transplantation

The establishment has a living kidney donor programme through which adult donors can donate a kidney to adult recipients. Potential donors usually come forward during a recipient's medical review. Additionally, the establishment also receives a number of enquiries from potential non-directed altruistic donors.

The living donor coordinator (the coordinator) calls potential donors to ascertain a brief medical history and to give them information regarding being an organ donor. They also arrange a suitable date for a clinic appointment to which they are encouraged to bring the potential recipient, if known. At the first clinic appointment, blood group testing takes place and virtual cross matching is started. Coordinators also go through a health questionnaire with potential donors which includes medical history, lifestyle and travel history questions. Potential living donors are informed about organ sharing schemes which may be available to them if they are not a suitable match for the potential recipient. If the potential donor still wishes to proceed and is a suitable match for the recipient, the living donor pathway is initiated, which takes approximately 18 weeks depending on the donor and any additional assessments that are required. Once a potential donor is identified, virology and cross matching assessments are undertaken.

Potential donors are given a tour of the renal wards during their day one appointment and baseline blood tests are undertaken and a booking made for kidney function tests. The potential donors also see a consultant nephrologist and a nephrology checklist is used to record all of the required donor characterisation assessments. Further organ and donor characterisation assessments are undertaken before the potential donor is discussed at the establishment's transplant multidisciplinary team (MDT) meeting. All potential donors must be discussed at least twice at the MDT before proceeding to donate however, potential donors are usually discussed around five to six times at the MDT prior to surgery due to additional characterisation assessments. As part of the live donor pathway, potential donors are seen by the surgeon who signs them off surgically. A second virology screen is undertaken on donors within 30 days of donation and an Independent Assessment is undertaken.

Following transplantation, the HTA-A and HTA-B forms are completed, signed, scanned and emailed to NHSBT. Living donors are reviewed by the establishment at two weeks, six weeks, three months, six months and 12 months post surgery. Following these visits they undergo annual follow up. Annual follow up can either be at their local medical centre or at the establishment via a nurse led transplant clinic. When discharging donors back to the care of their GP, the discharge letter includes a reminder to the GP that the donor has donated a

kidney and should they present in the future with a condition that may have an impact for the recipient, for them to contact the establishment.

Audit of Clinical Notes

During the establishment's audit, a review of recipient clinical notes and associated donor files was undertaken by the audit team as described below:-

- Three sets of clinical notes from recipients of cadaveric donor kidneys
- One set of clinical notes from a non directed altruistic living donor
- Clinical notes for a directed living donor and associated recipient

In all of these cases, where applicable, the following records were reviewed: donor consent, recipient consent, operation note, minimum data set form, living donor assessment forms, copy of EOS information, donor virology, repeat virology for living donors, cross match data, surgical and nephrology living donor sign offs, HTA-A and HTA-B forms, records of perfusion fluids used, packing and fluid record sheets, records of receipt, recipient checklist forms, fate of kidney if not transplanted form, and 'new donor paperwork checklist' forms.

In one set of cadaveric donor records a copy of the blood group sheet received with the organ had not been filed with the donor paperwork as expected, however records of donor blood group was recorded elsewhere (see advice below).

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.	General	The establishment has adopted the NOPs. Although adapted for specific use at the establishment, the establishment has created a suite of supplementary documents including procedural documents and various checklists to guide establishment staff and to record when checks are performed. The establishment is advised to append the supplementary documents and checklists to the relevant NOP so that establishment staff reviewing the NOPs are also able to access the relevant guidance and checklist documents.
2.	P3	The establishment is advised to review the temperature monitoring arrangements for the stored perfusion fluids and saline so that a procedure can be developed though which any excursions from the expected temperature ranges can be identified. Temperature monitoring should include monitoring of both the refrigerated fluid storage and the storage of the stocks of fluids at abient temperature. In reviewing the temperature monitoring procedures, the establishment may wish to consider the use of maximum and minimum temperature logging devices. Temperatures may then be checked regularly and upon removal of fluids from storage to verify that they have been stored at the correct temperature.

No.	Assessment Criterion	Advice
3.	I1	During the audit of clinical notes, an example of a donor blood group form that had not been filed with the donor paperwork as expected was found. The establishment is advised to consider if amending the current 'New document checklist' form to include a check of the donor blood group form may help to mitigate against the risk of the form not being filed with the donor paperwork as expected.
4.	GN2	In 2013 the establishment undertook an exercise through which all establishment staff involved in transplantation read the establishment's NOPs. In addition, staff recorded that they had read and understood the procedural documents. Once the NOPs have been amended as in advice item 1, the establishment is advised to ask all relevant staff to review the updated NOPs and to record that they have read and understood them. This may help to assure the establishment that all relevant staff have reviewed any updates made to the procedures, the supplementary guidance and checklist documents.

Concluding comments

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

- The review that the establishment undertakes of any organ offers that it declines.

- Positive comments about premises and exemplary practices helps the establishment in assuring itself that its acceptance and rejection criteria continue to remain appropriate.

- Staff from the H&I laboratory attend the establishment's living donor monthly meetings. This helps to assure the establishment that there is an opportunity for the laboratory to report any laboratory related incidents to the establishment.

- The forms created by the establishment to supplement the NOPs are useful in recording when various checks or procedures are undertaken. For example, the implanting surgeon signs the 'Recipient surgical checklist' form to record that they have undertaken a review of the donor and organ characterisation information in EOS prior to implantation.

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

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

Report sent for factual accuracy: 31 July 2018

Report returned with comments: 14 August 2018

Final report issued: 3 September 2018

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.

HTA assessment criteria

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.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
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.
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.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA or UKAS accreditation.

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.
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.
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.
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
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.
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.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.
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.
TP2) The organ shipping container is suitable for transport of the specified organ.
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.
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.
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.
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.

I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.
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.
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.
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
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.
Serious adverse events and adverse 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.
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.
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.
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.
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.
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.