Site visit audit report on compliance with HTA requirements
North Bristol NHS Trust

HTA licensing number 40048

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

25 and 26 January 2018

Summary of Audit findings

North Bristol NHS Trust (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to temperature monitoring, documentation and follow up of living donors.

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, 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 living	**OC, P, T, I**
Adult deceased	**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

North Bristol NHS Trust (the establishment) has been licensed 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 Renal Centre, based at Southmead Hospital, provides adult kidney services for the South West of England covering Dorset, Exeter and Gloucestershire. Transplant specialist nurses in Dorset and Exeter run transplant assessment clinics and in Gloucestershire, local nephrologists will speak to consultant nephrologists at Southmead about potential recipients and provide updates on their medical history. The establishment undertakes transplants of cadaveric donor organs. The establishment also has a living donor kidney transplant programme through which adult donors may donate their kidneys to adult or paediatric recipients. Paediatric transplants are undertaken at the University Hospitals Bristol NHS Foundation Trust. Transplant surgeons from Southmead Hospital hold honorary contracts with this Trust to undertake paediatric transplants. Details of transplant activities at University Hospitals Bristol NHS Foundation Trust are covered in the audit report under licence 40049. During 2016 to 2017 the establishment transplanted 30 kidneys from living donors and 99 kidney transplants from deceased donors.

Perfusion fluids used are stored in a fridge just outside the theatre suite. Theatre staff are responsible for monitoring the stock levels and ensuring that the perfusion fluids are in-date. The fridge is not temperature monitored, however it was noted that the perfusion fluid had a wide temperature storage range of 2 ˚C to 25˚C (see advice and guidance, item 1). Additional stocks of perfusion fluid are stored in a cupboard within the theatre suite area. The temperature of this area is monitored centrally.

Living Donor Kidney Transplants

Potential living donors may approach the establishment directly as a result of one of their relatives requiring dialysis or via referrals by a Nephrologist as a result of attending educational programmes. The establishment has also recently implemented an on-line screening tool for potential donors to complete as the first step to discover whether they could donate a kidney. In all cases, potential donors are asked to complete a medical questionnaire which is then reviewed by a Living donor coordinator. The questionnaire covers past medical and social history. The Living donor coordinator follows a Living donor Pathway document that charts the progression of the donor from initial assessment through to discharge following organ donation.

Potential donors are invited for a consultation with the living transplant coordinator. During this visit the potential donor will have bloods and a medical history taken. If the potential donor is a good cross match then they are invited for further medical investigations. The donor is then seen by a consultant nephrologist. The establishment has two firms of Nephrologists. This is to ensure that the donor and recipient are seen by separate Nephrologists. The establishment also ensures that there are at least four protected live donor clinics per month. Once all required test results are available, the Nephrologist will discuss the donor at a multidisciplinary team meeting (MDT). The outcome of this meeting is documented. If there is agreement to proceed the potential donor will then be have an appointment with a surgeon. The surgeon will discuss the risks of the procedure with the donor, use a checklist to determine whether the donor will undergo a key-hole or open surgery procedure, and a possible date for the procedure is discussed. The donor will then see an independent assessor and HTA approval sought. A final MDT is held after HTA approval has been obtained.

In theatre, prior to retrieval, the surgeon will check that the MDT form has been completed, HTA approval is in place and the World Health Organisation (WHO) checklist is completed. If the donation is part of the paired and pooled scheme then the living transplant coordinator will have liaised with NHS Blood and Transplant (NHSBT) beforehand to discuss arrangements between retrieval and transplant centres. This will include pre-booking of the NHSBT

contracted courier. Contact will be made with the surgeons to check if all centres are ready and there are no issues. The establishment has adopted the National Operating Procedure (NOP) 003 for the packing of the kidney (see advice and guidance, item 3). If the kidney is to be used at the establishment then the box is not sealed and will remain in theatre unless there are problems with the recipient, then the box will be sent to the renal ward. If the kidney is for a paediatric recipient then the kidney may be taken by taxi, to University Hospitals Bristol NHS Foundation Trust accompanied by either the transplanting surgeon or the living donor coordinator. If the kidney is unaccompanied then this will be transported by a NHSBT contracted courier. The recipient is not brought to theatre until the retrieval is complete and the retrieval surgeon has checked on the status of the donor.

Live kidney donors recover on the renal ward and are under the joint care of the Nephrologist and the surgeon. The donor has a pre-discharge discussion with the live transplant coordinator and given a leaflet on discharge. The Nephrologist will send a discharge letter to the donor's General Practitioner (see advice and guidance, item 2). The Transplant coordinator checks on the donor at least once a week for the following three weeks. Six weeks after discharge the donor is seen by a surgical consultant. This is followed by a six-month clinical assessment with the transplant coordinator and an annual follow up with a Nephrologist.

The establishment will consider donors from overseas but they will be carefully assessed to ensure that they will be able to access medical care, if required, post donation. Overseas donors remain in the country for at least four to six weeks after surgery.

Deceased Donor Kidney Transplants

One of the six transplant coordinator that is on-duty is contacted by the NHSBT Duty Office when an organ becomes available. The transplant coordinator will review the information on the electronic offering system (EOS) and assess the donor and organ characterisation information against the identified recipient or patients on the waiting list where applicable. The establishment operates a "Traffic Light Protocol" based on a local patient selection policy and whether the donation is after cardiac death (DCD) or after brainstem death (DBD). On this basis, if the offer is graded as red, the transplant coordinator can make the decision to decline the offer. Organs graded as green and amber are discussed with the on-call medical staff. Generally, however, the transplant coordinator will contact the on-call Consultant nephrologist to discuss the offer. The Consultant nephrologists have access to EOS mobile access and if required can review the donor information. If the offer is accepted by the Consultant nephrologist then the Consultant transplant surgeon is informed as part of the referral process. The Consultant, may also refer to EOS mobile to review the organ offer. Once both Consultant nephrologist and Transplant surgeon agree, the transplant coordinator will ring the Duty office to confirm acceptance of the offer. The Transplant coordinator will review EOS to monitor for any updates. The final decision whether to accept the organ is made when the Duty Office provides details of the anatomy of the kidney). All information and discussions are recorded by the Transplant coordinator in an offer/kidney import form.

The transplant surgeon would have previously discussed with the recipient the type of organ that may become available and the various risks and benefits in receiving, for example, an extended criteria organ. If minimum data criteria is not met, then the Consultant nephrologist and Transplant surgeon will consider the risk/benefit of whether to proceed or not. This decision is noted on the Establishment's electronic system.

Recipients on the waiting list for an organ are tissue typed by the Histocompatibility and Immunogenetics (H&I) laboratory every three months. The transplant coordinator will contact

the H&I laboratory to see if there is a virtual cross match or if a wet cross match is required. The recipient is contacted about the organ offer and asked about any sensitising events they may have experienced, such as blood transfusions. For an extended criteria kidney, the Consultant nephrologist and Transplant surgeon will discuss the offer with the patient and record the outcome of the discussion in the patient's notes.

The Transplant coordinator will notify the renal ward staff (RWS) of a kidney offer and the expected time of arrival. The RWS will enter the patient and recipient information on a kidney checklist form. The NHSBT courier delivers the organ(s) to the Renal ward where the nurse in charge will confirm the identity of the courier, check the integrity of the transport box accept and sign for the organ. The organ box is taken to the procedure room where two nurses will check the contents using a kidney check guide and complete the kidney checklist form and ensure that there is sufficient ice. If ice has to be topped up this is also recorded on the kidney checklist. Ice levels are checked every three hours and this check is recorded in the kidney checklist. A locked ice machine is located close to the renal ward and if this breaks down ice may be obtained from the Pathology department. The ice machine is cleaned weekly. The lymph, spleen and donor samples are sent to the on-site tissue typing laboratory. The RWS places the samples in a red specimen bag, completes the urgent sample form and attaches an "urgent" sticker. A porter is called on a number dedicated for urgent samples. The porter takes the donor samples directly to the Pathology department and places them in a dedicated urgent tissue typing box. The on-call Pathology technician signs the sample form and the porter will return this form to the renal ward. The RWS ensures that all documentation are completed, signed and retained with the appropriate kidney.

Prior to transplantation a porter will deliver the kidney box to theatre for back bench preparation. The Implanting surgeon will check that that the organ has been correctly transported and stored appropriately before commencing back benching. A sample of the perfusion fluid is taken and sent to the pathology department for microbial analysis. The surgical team follow the WHO checklist and is made aware of recent updates to EOS. At the end of the procedure information such as batches of perfusion fluid are recorded into the patient notes. The Transplant surgeon completes the HTA B form. All the paperwork that accompanies the organ i.e. the HTA form, donor blood group, kidney checklist and the HTA B form are taken by the Transplant surgeon to the surgeon's room and are placed in a secure drop box. The documents are collected and checked by a transplant coordinator who then scans and e-mails the HTA Form B to NHSBT.

The audit consisted of a visual tour that followed the pathway of the organ from receipt through to the implanting theatre and the donor testing laboratories.

Donor Testing

The audit included a visit to the Pathology laboratories where donor and organ characterisation assessments take place. This included H &I laboratory where tissue typing, virtual and wet cross matching takes place; the microbiology laboratory where the transport fluid which surrounds kidneys from deceased donors is sent for analysis and where blood samples are tested for HIV 1/2, HBV, HCV, HTLV 1/2, CMV, EBV, syphilis and *Toxoplasma* for living donors. The outcome of the microbial testing of the perfusion fluid is communicated to the transplant surgeon who in turn will inform NHSBT Duty Office if any microorganism is detected in the transport fluid as it may have implications for recipients of other organs from the same deceased donor. All laboratories are accredited by Clinical Pathology Accreditation (CPA) or United Kingdom Accreditation Service (UKAS).

Document Review

The electronic clinical notes relating to one living donor/recipient kidney transplants and two deceased donor kidney transplants were reviewed. Records of consent, mandatory test results, details of perfusion fluids used, core donor data forms and donor assessments were reviewed. The paper copies of the associated HTA A and HTA B forms and the living donor checklist were also reviewed. No anomalies were found. Additional documents relating to the Trust's procedure for the procurement of only CE marked devices, the audit of the sterile services and serious adverse event and serious adverse reactions (SAEARS) policy

Compliance with HTA assessment criteria

All applicable HTA assessment criteria have been assessed as fully met.

Advice

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

No.	Assessment Criterion	Advice
1.	P1	Although the perfusion fluid has a wide storage temperature range of 2°C to 25°C, the temperature of the fridge used to store the perfusion fluid is not monitored. The establishment is advised to consider using a maximum/minimum thermometer to record the storage fridge's temperature which could be reviewed daily and prior to any perfusion fluid being removed from storage. This would allow any temperature deviations to be detected, even if the operating temperature of the fridge has returned to normal following a deviation out of hours.
2.	R4	The establishment is advised to include a statement in the discharge letter for living donors which states that the GP should inform the establishment if, post donation, the donor develops a condition such as a malignancy, which may have implications for the wellbeing of the recipient. This is particularly important in cases of non-directed altruistic or paired and pooled donations where there is no direct relationship between the living donor and the recipient.
3.	CTP1	The establishment has adopted and adapted the National Operating Procedures (NOPS). The establishment is advised to review their standard operating procedure (SOP) 003 to include details for the labelling and re-packaging of organs from deceased donor.

Concluding comments

A number of good practices were observed during the audit. The establishment has a purpose built drop box where all transplant related documentation is deposited. This enables the transplant coordinator to collate, check and send appropriate forms to NHSBT in a timely manner. In addition to the SOPs, procedures such as receipt, packing or return of an organ are documented in a step by step format. All of these instructions are held in a distinct folder

on the renal ward as well as being available electronically. The establishment has a colour coding system for key forms that have to be completed in the living or deceased kidney transplant pathway. This greatly facilitated review of clinical notes during the audit. The establishment holds monthly meetings to review kidney offers that were declined by Southmead hospital and whether these organs were subsequently transplanted at other centres. The aim of these meeting is to

The HTA has given advice to the establishment with respect to temperature monitoring, record keeping and documentation.

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

Report sent for factual accuracy: 22 February 2018

Report returned with comments: 21 March 2018

Final report issued: 23 March 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.