

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

**University Hospitals Bristol NHS Foundation Trust**

**HTA licensing number 40049**

**Licensed for**

- **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.**

**25 and 26 January 2018**

**Summary of Audit findings**

The University Hospitals Bristol NHS Foundation 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 of perfusion fluids.

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 – Transplant activities

Organ type	Kidney
Paediatric	OC, P, T, I

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

## Background to the establishment and description of audit activities undertaken

The University Hospitals Bristol 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 kidney transplants for paediatric recipients, performing around 10 to 15 transplants per year.

The establishment is located at the Bristol Royal Hospital for Children which is where the kidney transplants take place. The establishment has a strong collaborative working

relationship with Southmead Hospital, North Bristol NHS Trust (HTA licensing number 40048) for kidney transplantation. Southmead Hospital carries out the following activities under its licence for this establishment:

- donor and organ characterisation testing for live donors;
- procurement of kidneys from live donors;
- tissue typing and cross-matching for both living and deceased donors;
- initial receipt and a preliminary visual inspection of a deceased donor kidney; and
- transportation of a kidney to the establishment.

Further details about these activities appear in North Bristol NHS Trust's audit report. In order to fully examine the close working between the two establishments, the audits of the HTA licences for the University Hospitals Bristol NHS Foundation Trust and the North Bristol NHS Trust were carried out on two consecutive days.

### **Deceased Donor Transplants**

Surgical staff undertaking the implantation of kidneys at the establishment are based at the North Bristol NHS Trust, Southmead Hospital and hold honorary contracts with the establishment. In addition, transplant coordinators who receive the organ offers for paediatric recipients are also based at Southmead Hospital.

The establishment's procedural documents have been developed in conjunction with Southmead Hospital staff and are broadly similar to Southmead Hospital's procedural documents. Minor adjustments have been made to reflect specific differences between the two sites. The establishment has also developed a collection of short, documented procedures for staff to follow, which provide step-by-step instructions relating to the different stages of the transplant process.

The area from which potential recipients are referred to the establishment includes the South West of England and South Wales. Clinics are run so that 'out of area' patients in England are seen by the paediatric nephrology team every four to six weeks either by paediatricians at their local hospital or the paediatric nephrologists at the establishment. In addition, outreach clinics are also held at local centres where patients are seen by a paediatrician and a nephrologist. Patients from South Wales are managed by their local nephrology team who discuss the patients with establishment staff via monthly video-linked multidisciplinary team meetings (MDT). Recipients are also seen, twice prior to transplant, by the establishment's nephrologists in dedicated transplant clinics.

Offers of kidneys from deceased donors are received by a transplant coordinator at Southmead Hospital. The coordinator uses the donor details given by the NHSBT Hub to access the donor and organ characterisation information from the electronic offering system (EOS). The coordinator records key donor and organ characterisation information onto a Donor Offer Form. Once the required characterisation information has been recorded, the coordinator contacts the on-call paediatric nephrologist and shares the kidney offer details, including the donor and organ characterisation information. If the paediatric nephrologist determines that the kidney offer is suitable for a recipient, the implanting surgeon is contacted and, again, kidney offer details including the donor and organ characterisation information is shared. The paediatric nephrologist and implanting surgeon review characterisation information in EOS and if necessary discuss the suitability of the kidney with each other. If the offer is considered suitable by both the paediatric nephrologist and implanting surgeon, it will be accepted and the coordinator confirms this with the NHSBT Hub.

The establishment is advised by the tissue typing laboratory whether the transplant can proceed on a virtual cross match; however, if the recipient is unsuitable for a virtual cross match, a wet cross match is performed prior to the transplant. The coordinator at Southmead

Hospital continues to liaise with the NHSBT Hub, staff involved in the transplant and the establishment's theatre department to confirm the expected timings of the transplant and arrange theatre times. The paediatric nephrologist meets with the anaesthetist to discuss the recipient and to alert them to any recipient related details that the anaesthetist should be aware of.

The kidney is taken to the renal ward at Southmead Hospital. Ward staff complete the Kidney Checklist form, the same form used for kidneys received for implantation into adult recipients at Southmead Hospital. As part of this process, the paperwork, ice levels in the organ transport box and donor details are verified against the details that the ward has been given about the donor to assure themselves that the correct kidney has been received and the storage conditions have been maintained during transportation. The lymph, spleen and donor blood samples are sent to the on-site tissue typing laboratory. The kidney is taken to theatres, either at Southmead Hospital or at the establishment, for inspection by the implanting surgeon. The surgeon verifies at this point the donor paperwork, donor identification and donor blood group. In addition, a sample of the fluid surrounding the kidney during transportation is taken and transported to Bristol Royal Hospital for Children with the kidney for analysis. Once the kidney has been prepared for implantation, it is re-packed, returned to the renal ward and transport to the Bristol Royal Hospital for Children is arranged. The kidney may be taken by taxi and is accompanied by either the transplanting surgeon or the transplant coordinator. If the kidney is unaccompanied, it is transported by an NHSBT contracted courier.

Paediatric transplantation is usually performed by two consultant transplant surgeons unless the recipient is an older adolescent, when only one surgeon may be needed. The paediatric nephrologist may join the pre-surgical briefing, where the procedure and recipient are discussed. Once again, the implanting surgeon verifies the paperwork that has accompanied the kidney, the recipient identification, donor details and the donor and recipient blood groups prior to commencing the implantation procedure.

Following the implantation surgery, the surgeon completes the operation record in the recipient's clinical notes. Transport labels, Kidney Checklist form, HTA-A and HTA-B forms are taken back with the surgeon to Southmead Hospital where they are placed in a secure drop-box for collection by the transplant coordinators. The relevant forms are then returned to NHSBT.

### **Living Donor Kidney Transplants**

The process regarding transplants of kidneys from living donors is very similar to the cadaveric pathway details above. Identification and work up of living donor's takes place at Southmead Hospital under their own HTA licence. This process can be reviewed in the report for the North Bristol NHS Trust (licence number 40048). Once retrieved, the living donor kidney is transported to the Bristol Royal Hospital for Children for implantation as described above.

### **Non-Directed Altruistic Living Donor Kidney Transplants**

The establishment does not undertake donor/organ characterisation and organ retrieval from non-directed altruistic living donors. During the audit it was learned that non-directed altruistic living donor organs that are not retrieved at Southmead Hospital are transported directly from the retrieving establishment to the Bristol Royal Hospital for Children for implantation. This means that the organ does not travel via Southmead Hospital and therefore, a Kidney Checklist form is not completed (see *Advice*, item 4).

## Audit Activities

As part of the site visit audit, the theatres where implantation takes place at the Bristol Royal Hospital for Children were visited. Perfusion fluid is stored in a pharmacy fridge located in theatres, which has its temperature monitored by theatre staff during working days. The fridge is also linked to an alarm system which will sound locally if the temperature deviates from the expected range. The theatres are staffed 24 hours a day, 7 days a week so alarms would be identified by theatre staff. Additional stocks of perfusion fluid are stored in a pharmacy store room (see *Advice*, item 2).

The establishment's laboratory that undertakes testing of the kidney's transport fluid is accredited by the UK Accreditation Service (UKAS) and the current accreditation certificate was reviewed during the audit. In addition, documentation demonstrating that the establishment's sterile services provider met the requirements of the assessment criteria was reviewed during the audit and were found to be satisfactory.

The audit of the establishment's licence included an audit of recipient clinical notes and where possible, the relevant donor files. A set of clinical notes and associated donor documentation was reviewed for a deceased kidney donor transplant. Recipient consent, donor details including identification, blood group and characterisation information were cross checked between documents. Perfusion fluid results, HTA-A, HTA-B forms and a kidney donor checklist form were also reviewed. A review of two further sets of clinical notes was also undertaken, one relating to a directed living kidney donor and one of a non-directed altruistic living kidney donor. Records as listed above for the deceased transplant were reviewed as applicable in each case. No anomalies were identified during the audit of the clinical notes.

## Compliance with HTA assessment criteria

The establishment was found to have met all applicable HTA assessment criteria.

## Advice

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

No.	Assessment Criterion	Advice
1.	CT3	The establishment is advised to liaise with North Bristol NHS Trust (Southmead Hospital) to amend the SOP relating to receipt of a cadaveric donor kidney prior to the organ being sent to the Bristol Royal Hospital for Children. This amendment should include detail that a sample of the fluid surrounding the organ during transport should be taken and then sent on to the Bristol Royal Hospital for Children with the kidney for analysis.
2.	P3	The establishment stores additional stocks of perfusion fluid in the pharmacy store room located in the theatre complex. Although the perfusion fluid has a wide storage temperature range of up to 25°C, the temperature of the store room was not monitored.  The establishment is advised to consider using a maximum/minimum thermometer to record the store room's temperature which could be reviewed prior to any perfusion fluid being removed from storage and placed

No.	Assessment Criterion	Advice
		into the monitored fridge. This would allow any temperature deviations to be detected, even if the temperature of the room had returned to normal following a deviation.
3.	TP1	The establishment has adopted and adapted the National Operating Procedures (NOPS). The establishment is advised to review and revise their standard operating procedure (SOP) 003 to include details of how kidneys from deceased donors should be re-packed if a kidney that has been received is not implanted and is sent to another transplant centre. This revision should also include how the transport box should be labelled.
4.	I2	Non-directed altruistic living donor kidneys arrive directly at the establishment and do not arrive via Southmead Hospital. During the audit of recipient clinical notes, it was found that as a result of the organ not travelling via Southmead Hospital, the Kidney Donor Checklist form was not completed as this is a Southmead Hospital form. The establishment is advised to consider replicating the Kidney Donor Checklist form, using it to record the same information as the Southmead Hospital form, when the establishment receives non-directed altruistic living donor kidneys directly in theatres.

### Concluding comments

Areas of good practice were observed during the audit. For example, the establishment works closely with the North Bristol NHS Trust and has developed good working relationships with staff at Southmead Hospital. In developing transplant procedures, many processes are aligned which helps to mitigate the risk that differing procedures between both establishments may give rise to confusion for establishment staff working under both licences.

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

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

**Report sent for factual accuracy: 23 February 2018**

**Report returned with comments: 2 March 2018**

**Final report issued: 3 April 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.
<i>Traceability – (these criteria apply to all licensed activities)</i>
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.
<i>Serious adverse events and adverse reactions (SAEARs) – (these criteria apply to all licensed activities)</i>
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.
<i>General – (these criteria apply to all licensed activities)</i>
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.