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

25 September 2013

Summary of Audit findings

University Hospitals Bristol NHS Foundation Trust (the establishment) was found to have met all applicable assessment criteria.

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 – 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

University Hospitals Bristol NHS Foundation Trust ('the establishment') carries out transplantation of kidneys for paediatric recipients. Transplant activity takes place at the Bristol Royal Hospital for Children, and up to 15 transplants from live, directed donors and from deceased donors take place there each year.

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, related donors;
- procurement of kidneys from live, related 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. References to the audit report for licence 40048 are made against some of the assessment criteria below. This establishment and Southmead Hospital were audited on consecutive days.

Organs transported from Southmead Hospital during normal working hours are accompanied by a surgeon or a transplant coordinator. Outside of these times, the organ will travel unaccompanied. Receipt of the organ on the Renal Ward is recorded by nurses on the 'Kidney checklist' and also, if the organ was unaccompanied in transit, on the courier's 'Transport Handover Form'. The slush-ice level will be topped up if it is considered to be necessary. The organ is stored in a secure room, from where it is collected by nursing staff or by a surgeon to be taken to theatres. Instructions for receiving an organ and topping up the slush-ice are kept on the Renal Ward.

After the organ has been implanted, the surgeon completes the HTA B form and returns it to Southmead Hospital, where it is filed in transplant records for 30 years. Transplant coordinators there fax a copy of the HTA B form to NHSBT Blood and Transplant (NHSBT) within seven days.

The establishment does not provide services to the National Organ Retrieval Service (NORS).

The auditors followed the pathway of a kidney arriving at the establishment, reviewed documentation, audited a sample of transplant records and had a round-table discussion with staff involved in transplantation.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
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.	This criterion is not applicable. The establishment is not responsible for obtaining information relating to deceased donors. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is not applicable. For living donors, donor and organ characterisation information specified in Part A of the Annex of the Directive is collected at Southmead Hospital under North Bristol NHS (NB NHS) Trust's HTA licence. Further information on the characterisation of living donors and organs is available in NB NHS Trust's audit report. For deceased donors, donor and organ characterisation information is collected by NHSBT.	**N/A**
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.	This criterion is fully met. Where it is considered necessary, the establishment may collect additional organ characterisation information, for example histopathological examination of a nodule found on a kidney.	**None**
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.	This criterion is fully met. All donor and organ characterisation information is retained at Southmead Hospital. There are documented procedures in place at Southmead Hospital to ensure that all such information is kept for a period of 30 years.	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Southmead Hospital performs donor and organ characterisation testing for living donors, as well as tissue typing and cross-match for deceased donors. That hospital's laboratories have full Clinical Pathology Accreditation (CPA). The establishment's Clinical Biochemistry, Histopathology and Haematology laboratories are CPA accredited. This was confirmed using the CPA's website.	**None**
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.	This criterion is fully met. Notification of a deceased donor kidney offer is received by a transplant coordinator at Southmead Hospital, who transcribes donor information from NHSBT's Electronic Offering System (EOS) onto an 'Offer form'. Following initial consideration by the transplant coordinator of the suitability of the offer, using a red-amber-green system based on donor criteria, a decision on accepting the offer is made by a paediatric nephrologist and a surgeon. The procedure is described in the establishment's 'Kidney transplant import protocol (paediatric)' document. The 'Kidney checklist', donor blood group and the HTA A form travel with the organ from Southmead Hospital. The implanting surgeon receives the immunological cross-match information from Southmead Hospital by email. The 'Donor and organ characterisation, assessment and allocation in deceased and living kidney donation and transplantation' standard operating procedure (SOP) states that the implanting surgeon must verify the donor and recipient identities, and the immunological cross-match information, prior to proceeding to implant a kidney.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
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.	This criterion is not applicable. The establishment does not procure organs from living donors. Information about procurement from living donors can be found in NB NHS Trust's audit report. For deceased UK donors, consent is sought by a SN-OD under NHSBT's licence.	**N/A**
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.	This criterion is not applicable. *Refer to assessment criterion R1.*	**N/A**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is not applicable. *Refer to assessment criterion R1.*	**N/A**
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.	This criterion is not applicable. *Refer to assessment criterion R1.* Information about living donor follow-up can be found in NB NHS Trust's audit report.	**N/A**

Assessment Criteria	Audit findings	Level of Shortfall
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.	This criterion is fully met. The requirement for all medical devices purchased by the Trust to be CE-marked is noted in the Trust's decontamination policy.	**None**
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. Reusable instruments are sterilised at another hospital within the Trust. There is a Trust-wide decontamination policy.	**None**

P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. HTA A forms are not used. The establishment does not procure organs from living donors. A deceased donor organ may be re-perfused, at the discretion of the surgeon. Details would be recorded on the HTA B form.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
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.	This criterion is fully met. Deceased donor organs are initially delivered to Southmead Hospital. The slush-ice level is topped up, and a visual inspection of the organ is carried out. The date and time of arrival of the organ are recorded on the 'Kidney Checklist'. Deceased donor organs to be transported from Southmead Hospital to the establishment are accompanied by a surgeon or a transplant coordinator during normal working hours, and are unaccompanied at other times. Organs from living donors are always accompanied in transit, as procurement at Southmead Hospital is during normal working hours. All organs are packed in NHSBT kidney boxes. Transportation is carried out by a specialist courier company. The 'Kidney checklist', donor blood group and the HTA A form travel with the organ from Southmead Hospital. If, upon receipt at Southmead Hospital, a kidney is assessed as unsuitable for the intended paediatric recipient, it will not be transported to the establishment, and would be re-offered. Transport arrangements are set out in the 'Kidney transplant import protocol (paediatric)' and the 'Packaging, labelling and transportation of organs in deceased and living kidney donation and transplantation' SOP. NB NHS Trust's audit report contains advice on adding a tick box to the 'Kidney checklist' to confirm verification of the driver's ID.	**None**

TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. *Refer to assessment criterion TP1.*	**None**
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.	This criterion is fully met. *Refer to assessment criterion TP1.*	**None**
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.	This criterion is fully met. *Refer to assessment criterion TP1.*	**None**
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.	This criterion is fully met. Southmead Hospital's laboratories are aware of the requirements for reporting serious adverse events. A sub-contractor of NHSBT's transport provider may, occasionally, transport organs from Southmead Hospital to the establishment. It is expected that this sub-contractor would report an incident which occurred during transportation, although this is not specifically documented. The NB NHS Trust audit report contains advice on this point.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
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.	This criterion is fully met. The 'Kidney checklist', donor blood group and the HTA A form travel with the organ from Southmead Hospital. The 'Donor and organ characterisation, assessment and allocation in deceased and living kidney donation and transplantation' SOP states that the implanting surgeon must verify the donor and recipient identities, and the immunological cross-match information, prior to proceeding to implant a kidney.	**None**

I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion is fully met. Deceased donor organs are initially delivered to Southmead Hospital. The slush-ice level is topped up, and a visual inspection of the organ is carried out. This is recorded on the 'Kidney Checklist'. If, upon receipt at Southmead Hospital, a kidney is assessed as being unsuitable for the intended paediatric recipient, it will not be transported to the establishment, and would be re-offered.	**None**
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.	This criterion is fully met. Decision-making on accepting an offer of a deceased donor organ is documented on the 'Offer form'. A risk-benefit analysis would be recorded in the recipient's operation notes. Further information can be found in the NB NHS Trust audit report.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
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.	This criterion is fully met. HTA A forms are not used. The establishment does not procure organs from living donors. The implanting surgeon completes the HTA B form and returns it, with all other transplant paperwork, to Southmead Hospital for filing. Transplant coordinators there fax the HTA B form to NHSBT. This process is described in the establishment's 'Kidney transplant import protocol (paediatric)'. Further details on procedures for return of HTA B forms to NHSBT can be found in NB NHS Trust's audit report.	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. All living donors and recipients are identifiable by their full name, hospital number and date of birth. Deceased donors are identifiable by their NHSBT donor number, which is recorded in EOS and on the HTA A form.	**None**

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.	This criterion is fully met. The date and time of arrival of the organ are recorded on the 'Kidney Checklist'. For an organ that is unaccompanied in transit from Southmead Hospital, receipt of the organ on Renal Ward is also recorded on the courier's 'Transport Handover Form'. *The HTA has given advice against this criterion.*	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Serious adverse events and 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.	This criterion is fully met. Incidents are reported internally using the Trust's online incident management system. The establishment has an SOP for notifying NHSBT of a serious adverse event or adverse reaction (SAEAR), which is an adaptation of NHSBT's SOP3888/1. A surgeon would be responsible for making a SAEAR notification to NHSBT.	**None**
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.	This criterion is fully met. *Refer to assessment criterion S1.*	**None**
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.	This criterion is fully met. Southmead Hospital's laboratories are aware of the requirements for reporting serious adverse events. A sub-contractor of NHSBT's transport provider may, occasionally, transport organs from Southmead Hospital to the establishment. It is expected that this sub-contractor would report an incident which occurred during transportation, although this is not specifically documented. The NB NHS Trust's audit report contains advice on this point.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
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.	This criterion is fully met. Personnel involved with transplantation are registered with the appropriate healthcare professional regulatory body. New staff at the Trust receive corporate and local inductions. Renal Ward nurses have received training on organ receipting procedures. Transplantation is a consultant-led service. Roles and responsibilities for transplantation staff are clearly described in the relevant SOPs.	**None**
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.	This criterion is fully met. *Refer to assessment criterion GN1*.	**None**
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.	This criterion is fully met. *Refer to assessment criterion GN1.*	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	TC3	If a deceased donor organ is unaccompanied during its journey from Southmead Hospital, the renal ward nurse receiving the organ has to sign the courier's 'Transport Handover Form' to confirm receipt. The auditors found one example where the handover form was not signed. The HTA advises the establishment to remind staff periodically of the documented procedure for receipt of organs, to ensure that these are followed.

Concluding comments

The establishment has met all applicable assessment criteria. Several areas of strength were identified during the audit. There is a strong collaborative working relationship with North Bristol NHS Trust in all aspects of transplantation activity. The Trusts have worked closely when adapting the National Operating Procedures to ensure these are harmonised across both establishments.

Examples of good practice include:

- patient folders containing transplant operation notes have a red and white sticker placed on the cover to indicate these must be retained for 30 years; and
- transplant coordinators conduct ‘snap audits’ to confirm that ‘Kidney checklists’ are returned, and that all required data has been collected.

The HTA has given advice to the establishment on reminding staff of documented procedures for receipting organs.

Report sent for factual accuracy: 14 October 2013

Report returned with comments: No comments on factual accuracy were received from the establishment

Final report issued: 11 November 2013

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.