Site visit audit report on compliance with HTA requirements

University Hospitals Birmingham NHS Foundation Trust

HTA licensing number 40042

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

10 December 2013

Summary of Audit findings

At a pilot audit of University Hospitals Birmingham NHS Foundation Trust ('the establishment') in October 2012, the HTA assessed many assessment criteria as fully met based on Trust processes and documentation in place at that time. For some criteria, operating procedures were not yet fully documented. At the December 2013 audit, the auditors focussed on those assessment criteria where documented operating procedures are required.

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 – Procurement activities

Organ type	Heart	Lung	Liver	Kidney	Pancreas
Adult deceased	**P, T, R**	**P, T, R**	**P, T, R**	**P, T, R**	**P, T, R**
Paediatric deceased	**P, T, R**	**P, T, R**	**P, T, R**	**P, T, R**	**P, T, R**
Adult living	**-**	**-**	**DC, OC, P, T, R**	**DC, OC, P, T, R**	**-**

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

Licensable activities carried out by the establishment – Transplant activities

Organ type	Heart	Lung	Liver	Kidney
Adult	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**	**OC, P, T, I**

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

Background to the establishment and description of audit activities undertaken

University Hospitals Birmingham NHS Foundation Trust ('the establishment') performs cardiothoracic and abdominal (kidney, liver) transplants. Transplantation takes place at Queen Elizabeth Hospital, Birmingham, for adult patients only. The establishment provides staff to the National Organ Retrieval Service (NORS) for cardiothoracic and abdominal organ retrievals, and enjoys a strong collaborative working relationship for organ transplantation with Birmingham Children's Hospital (HTA licensing number 40051).

The HTA carried out a pilot audit of the establishment in October 2012. Several assessment criteria were assessed as fully met, based on Trust processes and documentation in place at that time. Criteria where operating procedures were not fully documented were assessed as almost or partially met. Since the pilot, the establishment has adopted, without modification, NHS Blood and Transplant's (NHSBT's) National Operating Procedures (NOPs) NOP001-NOP006 as standard operating procedures (SOPs) CG019-CG024. These SOPs cover cardiothoracic and abdominal transplantation activities. A range of additional flowcharts and checklists describing local procedures for kidney, liver and cardiothoracic transplantation to supplement these SOPs is in place.

The December 2013 audit focussed on assessment criteria where documented operating procedures are required. The auditors reviewed documentation, had round-table discussions with staff working in transplantation, and audited a sample of transplant records. Tours of organ pathways were performed at the pilot audit and were not repeated. Criteria that were assessed as fully met at the pilot audit were not re-assessed; some findings from that audit are contained in this report.

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.	The establishment is not responsible for obtaining information relating to a deceased donor. 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 fully met. This criterion is applicable for living donors. For kidney and liver lobe donors, the establishment has recently developed a 'Minimum data set for donors' checklist, which lists the donor information in Part A of the Annex to the Directive to be collected. Donor and organ characterisation information for kidney donors may, in some cases, be gathered initially at regional referral centres. Those centres record such information using locally developed forms, which differ in format from centre to centre. *The HTA has given advice against this criterion*	**None**
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 considered appropriate, additional donor and organ characterisation tests may be performed at the establishment or at a retrieval centre.	**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. At the pilot audit it was verified that the Trust record retention policy states this requirement. The establishment has also adopted NHSBT's NOP006 as SOP CG024 'Transfer and storage of donor and organ characterisation information and storage of traceability data'.	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. At the pilot audit the CPA accreditation status of the NHSBT histocompatibilty and immunogenetics laboratory used for tissue typing, and the establishment's virology and histopathology laboratories, was verified.	**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 the potential offer of a cardiothoracic organ, or of an abdominal organ from a deceased after brain death (DBD) donor, will come from NHSBT; offers of abdominal organs from deceased after circulatory death (DCD) donors come from a SN-OD. The transplant coordinator who is notified of the offer will log onto NHSBT's Electronic Offering System (EOS) to access core donor data, transcribe it to local forms, and contact a consultant surgeon, who may accept or decline the offer based on this data, or request additional tests or information, as required. Potential living kidney or liver lobe donors provide medical and behavioural information, and undergo detailed physiological investigations, to establish their suitability to become a donor. Initial assessment of some kidney donors may take place at regional referral centres, liver lobe donors are assessed only at the establishment. Live donors and recipients are discussed at multidisciplinary team meetings. The establishment has adopted NHSBT's NOP006 as SOP CG024, and NOP001 as SOP CG019 'Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation'. A cardiothoracic 'Operative procedure setup', 'Recipient transplant coordinator kidney setup guidelines' and a 'Living donor kidney pathway', sets out local procedures for these organ types. The 'Imported altruistic kidney' and 'Paired/pooled exchange protocol' SOPs explain receipt of donor and organ characterisation information from other centres for altruistic, and paired/pooled, kidney transplants respectively. *The HTA has given advice against this criterion*	**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 fully met. For deceased UK donors, consent for procurement is sought by SN-ODs working under NHSBT's licence (HTA licensing number 40056). Consent forms are reviewed during the pre-operative surgical pause for living and deceased donor retrievals.	**None**
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 fully met. At the pilot audit it was verified that the Trust Medical Device Policy refers to the relevant European legislation. The establishment has adopted NHSBT's NOP004 as SOP CG022 'Management of procurement material and equipment in living and deceased donation and transplantation'.	**None**
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 fully met. Reusable instruments are sterilised by the Trust sterilisation services department. It was verified at the pilot audit that this facility had current validation certification. The establishment has adopted NHSBT's NOP004 as SOP CG022 'Management of procurement material and equipment in living and deceased donation and transplantation'.	**None**
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 fully met. Donors may telephone a transplant coordinator at any time if they experience discomfort following procurement. Kidney and liver lobe donors have a series of follow-up appointments at the hospital in the first six months after donation, and receive a detailed discharge summary letter. Subsequently, follow-up assessments are conducted annually either in the UK or, for some kidney donors, in their overseas country of origin. *The HTA has given advice against this criterion*	**None**

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. *Refer to assessment criterion R2.*	**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. *Refer to assessment criterion R3.*	**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. An audit of a sample of cardiothoracic and abdominal transplant records confirmed that batch numbers and expiry dates of perfusion fluids were recorded on the appropriate HTA A and B forms.	**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. The establishment has adopted NHSBT's NOP003 as SOP CG021 'Packaging labelling and transport of organs in deceased and living donation and transplantation'. Retrieval and transportation of deceased donor organs follows national NORS protocols. The 'Recipient Transplant Coordinators kidney setup guidelines' explains how a deceased donor kidney that is being re-offered into the national pool is prepared in readiness for transportation to another centre. Kidneys are transported in standard NHSBT boxes that are labelled according to the accompanying instructions. Lifeport kidney perfusion devices are available, but are not used for transportation. Livers and cardiothoracic organs are transported in proprietary cool boxes. An NHSBT-commissioned courier, or a subsidiary, is used for transportation. The courier is contractually obliged to report a serious adverse event occurring during transportation.	**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. *Refer to assessment criterion TP1.*	**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 establishment has adopted NHSBT's NOP002 as SOP CG020 'Verification of donor identity, consent/authorisation and organ and donor characterisation in deceased and living donation and transplantation'. The 'Imported altruistic kidney' and 'Paired/pooled exchange protocol' SOPs explain receipt of donor and organ characterisation information from other centres for altruistic, and paired/pooled, kidney transplants respectively. The Trust 'Surgical safety checklist' has been adapted for liver transplantation so the implanting surgeon must confirm the donor and recipient blood groups prior to implantation, which is an example of good practice. *The HTA has given advice against this criterion*	**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. The ice-slush level of a deceased donor kidney received onto Ward 305 may be topped up if it is considered necessary.	**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. At the pilot audit it was verified that a risk-benefit analysis would be conducted by the implanting surgeon, and recorded in the recipient's notes, in such instances.	**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. Transplant coordinators will return HTA A and B forms to NHSBT within seven days. The establishment has adopted NHSBT's NOP006 as SOP CG024. *The HTA has given advice against this criterion*	**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. Deceased donors are traceable by their NHSBT donor number, which is on EOS and will be noted on the HTA A form. Living donors and recipients are identifiable by their full name, date of birth and hospital number.	**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. Such information is recorded on logs kept in Ward 305 (for deceased donor kidneys) or in theatres (for all other organs).	**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. Staff are fully conversant with the requirement to report incidents within the Trust using the online Datix system and also, where relevant, to NHSBT. The establishment has adopted NHSBT's SOP3888/1 as SOP CG026 'Reporting an organ donation or transplantation incident to NHSBT'. Recipient transplant coordinators also have a flowchart on reporting incidents to NHSBT. The NHSBT-commissioned courier company is contractually obliged to report a serious adverse event occurring during transportation.	**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. *Refer to assessment criterion S1.*	**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. All transplant activity is consultant-led. The establishment has adopted NHSBT's NOP005 as SOP CG023 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation'; staff roles and responsibilities are also set out in locally developed flowcharts. Staff are registered with the appropriate healthcare regulatory body and undertake continuing professional development to maintain their registration. Some examples of surgical and nursing staff appraisal and competency records were seen at the pilot audit; further examples were not reviewed at this audit.	**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.	CT2	For some living kidney donors, characterisation information specified in Part A of the Annex to the Directive may be collected at regional referral centres. The auditors noted that forms developed to gather such information varied in format between the referral centres. The HTA advises the establishment to consider how characterisation information can be recorded in a standardised, unambiguous, format across all referral centres.
2.	CT6	The HTA advises the establishment to state in the 'Paired/pooled exchange protocol' the donor serology test results (i.e. hepatitis B, hepatitis C and HIV) an implanting surgeon should verify prior to a live donor kidney being transported from another centre.
3.	CT6, R2, P1, TP1, TP4, TC1	The establishment has adopted, without modification, NHSBT's NOPs NOP001-NOP006 as SOPs CG019-CG024. Flowcharts and checklists describing local practices for cardiothoracic and abdominal transplantation support these SOPs. The HTA advises the establishment that the SOPs could be further strengthened as reference documents for the transplant service as follows: • citing local flowcharts and checklists by name or reference number within the SOPs. This is beneficial as local processes and documentation differ between the various organ types; • citing relevant Trust policies, such as for retention of medical records and procurement of medical devices and equipment; • specifying that transplant coordinators will return HTA A and B forms to NHSBT within seven days and the method by which forms are to be returned.
4.	I1	The Trust 'Surgical safety checklist' has been adapted for liver transplantation to include a check-box for the implanting surgeon to record their verification of donor and recipient blood groups and their compatibility. The HTA advises the establishment to apply this example of good practice to surgical safety checklists for other transplant procedures. Check-boxes could, for example, be used to record that the surgeon has verified the donor's blood group and virology results, the HTA A form and EOS information.
5.	TC3	The HTA advises that the flowchart explaining what to do when receiving a deceased donor kidney onto Ward 305 should remind nurses to complete the 'Ward 305 Organ Fridge Audit Form', as set out in the 'Guidelines for Ward 305 Nurse in Charge – kidney delivered for transplantation'.
6.	R4	The establishment is advised to state in the discharge letter sent to the donor's medical practitioner that the establishment should be contacted if a donor experiences a serious adverse reaction which may have resulted from the organ donation, or which may have a potential impact on the recipient's health, such as development of a transmissible infection or a malignancy.
7.	-	The auditors met with surgeons who outlined proposals for two new programmes – small bowel transplantation for adult recipients, and hand/lower arm transplantation. It is anticipated such activity would not commence for some months. The HTA advises the establishment, prior to commencing any such new activity, to review and update its SOPs, flowcharts and checklists to

		include specific information relevant to these activities. For example, the collection of donor and organ/composite tissue characterisation information, surgical roles and responsibilities at retrieval, the recording of traceability data at retrieval and implantation, and the packaging and labelling of the organ/composite tissue, should be clearly documented. Surgeons who will perform hand/lower arm retrievals may also wish to observe NORS retrievals, to become familiarised with procedures and staff responsibilities. The establishment is further advised to notify the HTA once it has developed its proposals further, and prior to commencing any such new activity, so the HTA can decide whether to conduct a focussed site visit audit.

Concluding comments

The establishment has met all applicable assessment criteria. The close engagement of the Clinical Governance group with the transplant teams, and the clear communications across all teams, were notable aspects of strength identified by the auditors. The establishment has augmented the SOPs, which are modelled on NHSBT's NOPs, with locally developed flowcharts and checklists for specific organ types and processes. The auditors are grateful for the cooperation and courtesy shown throughout the audit by staff from the establishment.

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

Report sent for factual accuracy: 10 January 2014

Report returned with comments: 27 January 2014

Final report issued: 27 January 2014

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.