Site visit audit report on compliance with HTA requirements

Royal Liverpool and Broadgreen University Hospitals NHS Trust

HTA licensing number 40031

Licensed for

- **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)**

- **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

5 June 2013

Summary of Audit findings

The Royal Liverpool and Broadgreen University Hospitals NHS Trust (the establishment) was found to have met all 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	Kidney
Adult living	**DC, OC, P, T, R**

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

Licensable activities carried out by the establishment – Transplant activities

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

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 establishment has a dedicated kidney transplant unit based at the Royal Liverpool Hospital. The establishment completed 99 transplants in the last financial year. Of the kidneys transplanted, approximately one third were from live donors. Kidneys from deceased donors were received from donors deceased after circulatory death (DCD) approximately 50% of the time and from donors deceased after brain death (DBD) the other 50% of the time. The establishment does not participate in the National Organ Retrieval Service for organs from the deceased. It retrieves kidney as part of its living kidney transplant service.

The kidney transplant ward has 14 beds. The unit will move to new hospital premises in 2017. The ward capacity is anticipated to increase to 18 beds. Donors and recipients recover post-transplant in the ward. On rare occasions patients may spend some time in the critical care unit following transplant. The establishment has full daily theatre access and after-hours access to the hospital's emergency theatre.

The establishment closely monitors its recipient list through regular Multidisciplinary Team (MDT) Meetings. By assessing recipients on a regular basis the recipient list is kept as updated as possible, prior to kidney offers.

Offers for deceased kidneys are received by recipient coordinators from NHS Blood and Transplant (NHSBT) specialist nurses for organ donation (SN-ODs) within normal business hours and registrars out of hours. For DCD donations SN-ODs call with an initial assessment. The transplant coordinators or registrars fill out a donor referral form to assess the offer. The transplant coordinators or registrars liaise with transplant surgeons to find a suitable surgeon. The consultant nephrologist is involved in very complicated cases. If the offer is accepted the consent will go ahead and the information will be received on NHSBT's Electronic Offer System (EOS). For DBD donations, the SN-OD will phone the recipient coordinator with a name and donor number available for a named recipient at the establishment. The recipient coordinator liaises with the surgeon or registrar and if the offer is accepted all the information is provided on EOS.

The recipient coordinator liaises with the respective SNOD to arrange transport. Kidneys from the deceased are taken by drivers of the transport provider contracted by the establishment, directly to the transplant ward. Ward staff check the integrity of the box and sign the organ in. The ward staff contact the recipient coordinator. The recipient coordinators do not work outside of normal working hours, so the ward staff contact the assigned registrar out of hours. The recipient coordinator or registrar on duty will contact the virology and immunology units to arrange testing. The kidney is placed in a secure room directly opposite the ward desk and the lymph nodes and spleen are placed in a fridge in the room. The hospital's in-house laboratory staff collect the lymph nodes and splenic tissue for testing and cross-match. All paperwork is kept with the organ in the box to prevent mix-up of multiple organs received at the same time.

The establishment has received a kidney donation from France. The accompanying paperwork included UK equivalent forms, detailing the donor and organ characterisation information and details about the retrieval.

For living kidney transplant, the donor and recipient surgeries take place in two adjoining theatres, with separate surgical teams. For living operations, the kidney is double-bagged, put on melting ice and transported between theatres in an NHS Blood and Transplant (NHSBT) organ box.

This was the first, routine audit of the establishment. The audit included a tour of the premises, document review and discussions with recipient coordinators, living organ coordinators, quality management staff, a consultant nephrologist and a transplant surgeon.

The establishment had an action plan issued with its continuous licence. This required adoption or adaption of a number of documents to support its practices. The actions taken were assessed during the audit. The action plan was assessed as fully met and will be closed.

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 SN-OD under the NHSBT 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. All mandatory information was seen in patient notes. Recipient coordinators print out NHSBT EOS forms and keep them on file. For living donors, mandatory information was collected in the pre-operative assessment by the clinic.	**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. As above.	**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. The establishment has in place national operating procedure (NOP)006, *Transfer and storage of donor and organ characterisation, information and storage of traceability data* adopted as part of the *Trust Policy: clinical governance and quality department: policy for the development of trust policies, protocols and procedures NOP006.* NOP006 is supported by the *Trust Informatics Policy: Informatics – records management policy.* This references transplantation records and requires that "records not otherwise kept or issued to patient records that relate to investigations or storage of specimens relevant to organ transplantation should be kept for 30 years."	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The establishment uses its own on-site Histocompatibility and Immunogenetics (H&I) and virology laboratory. This has Clinical Pathology Accreditation (CPA). A certificate (CPA Ref No. 2944) was seen during the audit.	**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. The establishment has in place NOP006, *Transfer and storage of donor and organ characterisation, information and storage of traceability data adopted as part of the Trust Policy: Clinical Governance and Quality Department: Policy for the development of trust policies, protocols and procedures NOP006.* A transplant surgeon confirmed that he receives the information before the retrieval takes place and has time to review the donor and organ characterisation information before the implantation.	**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. The consent process for living donors is delivered in multiple stages. Donors approach the transplant coordinators separately from the recipients. Donors sign consent forms for options if a kidney cannot be transplanted.	**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. The establishment has in place NOP004, *Management of procurement material and equipment in deceased and living donation and transplantation: adapted as Trust Policy: Clinical Governance and Quality Department.* This is supported by the *Trust operational policy: Clinical Governance and Quality Department: introduction of a new technique or medical device*. This requires all new devices and techniques to be assessed by the Techniques and Medical Devices Group. The *Trust Operational policy: medical engineering – medical devices management and decontamination policy and procedures* specifies that “non CE-marked products should not be considered for loan or use.”	**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. There is a *Trust Operational policy: medical engineering – medical devices management and decontamination policy and procedures* in place. This refers to general principles of decontamination and sterilisation undertaken by the in-house Central Cleaning and Decontamination Unit (CCDU). A validation certificate for: provision of medical device support for the Royal Liverpool and Broadgreen University Hospital Trust including the management, maintenance and repair of medical devices as well as provision of user training and specialist support activities, from the UK Accreditation Service (Cert: FS28629) confirmed the quality management system (QMS) compliance with ISO9001:2008. A Det Norske Veritas (DNV) Business Assurance Management System Certificate demonstrated conformity with QMS standard ISO13485:2003 for the cleaning, maintenance, packing and sterilisation of procedure packs and surgical instruments. A DNV Certificate of Assessment – EC (Cert No. 8356-2007 CE-NOR) demonstrated the quality system for procedure packs, surgical instruments and linen manufactured by the CCDU complies with the requirements of the Directive.	**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. The establishment makes endeavours to follow-up living donors for the purpose of identifying relevant reactions. This includes following up donors once after six weeks and once every year to check on kidney function and blood pressure. Advice is provided below.	**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. Reference is made to 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. Reference is made to 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. The establishment has in place NOP006, *Transfer and storage of donor and organ characterisation, information and storage of traceability data adopted as part of the Trust Policy: Clinical Governance and Quality Department: policy for the development of trust policies, protocols and procedures NOP006.* Evidence of records of perfusion fluid and batch numbers was seen on copies of HTA forms during the audit. To ensure batch numbers are recorded, a section of the operation notes includes a specific field for perfusion batch numbers. Theatre staff record this in the notes and recipient and living coordinators transfer this onto HTA forms after the transplant.	**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. *NOP003, Packaging, labelling and transport of organs in deceased and living donation and transplantation adopted as Trust Policy: Clinical Governance and Quality Department* is in place. The integrity of the organ container is checked by ward staff on arrival and details are recorded on the Transplant Information Form.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses NHSBT transport boxes. This includes use of the box for transport between adjoining theatres during living kidney operations.	**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. The establishment has in place, NOP006 *Transfer and storage of donor and organ characterisation, information and storage of traceability data adopted as part of the Trust Policy: Clinical Governance and Quality Department: Policy for the development of Trust Policies, protocols and procedures NOP006.*	**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. *NOP003, Packaging, labelling and transport of organs in deceased and living donation and transplantation adopted as Trust Policy: Clinical Governance and Quality Department* is in place.	**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. There is a service level agreement (SLA) in place for the Provision of Transportation Services for Transplantation. This specifies that "staff are to comply with HTA and user local processes to ensure HTA licence requirements are met." And requires transport staff to, "comply with the relevant standards as set out in the NOPs." The establishment confirmed that it has discussed this with its transport provider and staff are aware of the need to report. The transport provider offered a driver to be on-call to address any questions or concerns relating to transport which could arise during the audit.	**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 in place NOP006, *Transfer and storage of donor and organ characterisation, information and storage of traceability data adopted as part of the Trust Policy: Clinical Governance and Quality Department: Policy for the development of Trust Policies, protocols and procedures NOP006.*	**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 integrity of the organ container is checked by ward staff on arrival and details are recorded on the Transplant Information Form. Compliance with the conditions of preservation and transport is confirmed by theatre staff and the surgeon.	**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. A transplant surgeon confirmed that any risk-benefit analysis would be discussed with a patient and recorded in the notes.	**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. The establishment has in place NOP006, *Transfer and storage of donor and organ characterisation, information and storage of traceability data adopted as part of the Trust Policy: Clinical Governance and Quality Department: Policy for the development of Trust Policies, protocols and procedures NOP006.* Staff confirmed all forms are returned within days of the transplant. The recipient and living coordinators track the document pathway using the transplant recipient information form and the living related / unrelated information form.	**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. The establishment has in place NOP006, *Transfer and storage of donor and organ characterisation, information and storage of traceability data adopted as part of the Trust Policy: Clinical Governance and Quality Department: Policy for the development of Trust Policies, protocols and procedures NOP006.* The establishment tracks all donors, recipients and organs using names and identification numbers.	**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. Reference is made to CT4. There is a *Trust Clinical Policy for Human Tissue Disposal*. The establishment maintains separate records for any organs disposed of, with reasons.	**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. The establishment has in place *Trust Policy: Clinical Governance Quality Department: Policy for the Development of Trust Policies, Protocols and Procedures SOP3888*. Staff are aware of this. This SOP is also referenced in the *Trust Operational Policy: Risk Management Department, Incident Reporting Policy and Procedure* (Pol ref. 3188).	**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. Reference is made to 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. The establishment uses its own H&I and virology laboratories. The laboratory is CPA accredited. Incidents are reported through the hospital's internal electronic system. The establishment staff have close working relationships with transport providers and an SLA is in place requiring compliance with HTA requirements.	**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 new staff in the kidney transplant ward are provided with induction and ongoing training based on observation. The establishment maintains a training register, including dates of registration for nurses. The hospital's human resources unit maintains a register of surgical staff qualifications, such as ensuring up to date General Medical Council registration and revalidation and membership of the Royal College of Surgeons.	**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. Reference is made to GN1. Advice is provided below.	**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. The establishment has a *Trust Policy: Clinical Governance and Quality Department Policy for the development of trust policies, protocols and procedures NOP005* in place.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	R4	The establishment makes endeavours to follow-up its donors after transplants, such as sending a letter of discharge to the donors' general practitioner and / or referring centre. In the unlikely event that a donor organ is not able to be implanted into the intended recipient, a donor may choose the option to offer the organ for allocation into the national pool. A donor could also be an altruistic donor. In such situations, identification of reactions in the donor, that had a potential consequence for the recipient, would be harder to trace without strong follow-up procedures. The establishment is advised to review its discharge letter and ensure the references to reporting serious adverse reactions that may be related to the donation or may affect the recipient are clearly articulated.
2.	TP4	The establishment has a protocol in place to manage reallocation. The audit team were advised that when a kidney is reoffered to the national pool the surgical team instructs the H&I laboratory to stop testing. The establishment's protocols do not include a reference to this. The establishment should update its protocols to reflect the needs to include any tests already completed by the H&I laboratories with the organ. While the Clinical Director has regular meetings with H&I laboratory staff, the establishment may wish to consider including H&I team members in the wider MDT meetings.
3.	GN2	As the establishment has a dedicated transplant unit, there is a good induction and ongoing training process in place for staff directly involved in the transplant chain. Recipient coordinators are not present out of hours. Out of hours, circulating registrars take on a similar role. A recent incident out of hours at the establishment was due to miscommunication with a member of hospital staff who said they were less familiar with the process. The establishment may wish to consider a general transplant unit induction / training package specifically designed for staff who are involved in the transplant process on a less frequent basis.

Concluding comments

The establishment benefits from a dedicated transplant unit. As staff members are substantially involved only in transplant activities, the establishment has time and expertise to dedicate toward specialised monitoring of its recipient list. When an offer for a deceased kidney comes in, the updated recipient list allows for smooth decision-making by recipient coordinators, surgeons, nephrologists and registrars. There is good communication across the unit and the establishment maintains strong links with the hospital laboratory and transport providers.

The establishment has a good training and induction programme for staff directly involved in transplant activities. There is a weekly journal club related to transplant and regional education meetings are attended by all regional referring centres.

The establishment has very strong record-keeping in place to maintain traceability. This is maintained by the transplant and recipient coordinators through the use of checklists such as the Living Related / Unrelated Information Form, the Transplant Recipient Information Form and the Transplant Information Form, to track the pathway of the organ and related documents. The establishment also maintains separate records for disposed organs with the reasons for disposal. This practice is in line with the HTA code of practice on disposal.

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

Report sent for factual accuracy: 10 July 2013

Report returned with comments: 1 August 2013

Final report issued: 1 August 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.