Site visit audit report on compliance with HTA requirements

Belfast Health and Social Care Trust

HTA licensing number 40046

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

17 October 2013

Summary of Audit findings

Belfast Health and Social Care 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 – 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	**OC, P, T, I**
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

Belfast Health and Social Care Trust ('the establishment') is a single-organ centre (kidneys) providing transplant services for adult and paediatric patients. Transplant activity takes place at two hospital sites within the Trust. Procurement of kidneys from living adult donors, and implantation of kidneys for adult recipients, takes place at Belfast City Hospital. Implantation of kidneys for paediatric recipients takes place at Belfast Hospital for Sick Children.

Kidneys from deceased and altruistic living donors where procurement takes place elsewhere, are delivered to City Hospital. A kidney for a paediatric recipient is transported from City Hospital to the Hospital for Sick Children by a specified taxi firm. Donor and organ characterisation, testing for living donors and, where necessary, histopathology on donor kidneys, are performed by the establishment. The establishment does not provide services to the National Organ Retrieval Service (NORS).

The establishment has adopted all of NHS Blood and Transplant's (NHSBT's) National Operating Procedures (NOPs), adapted them to reflect local practices, and amalgamated them into a single overarching document, 'The quality and safety of organs intended for transplantation'. This document is reviewable annually, with its next review due in December 2013.

During the audit, the auditors followed the pathway of a kidney received into City Hospital, and its transfer to the Hospital for Sick Children. Policies and procedures, and a sample of transplant patient records, were reviewed, and round-table meetings with staff involved in transplantation took place. An anomaly noted during the patient records audit (an HTA A form number was not transcribed onto the corresponding HTA B form) did not impact upon traceability. No other discrepancies were noted.

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. Donor and organ characterisation information specified in Part A of the Annex to the Directive, detailed in HTA's 'The quality and safety of organs intended for transplantation – a documentary framework', is collected during donor work-up.	**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, donor and organ characterisation information specified in Part B of the Annex to the Directive, detailed in HTA's 'Guide to quality and safety of organs intended for transplantation – a documentary framework', will be collected. *The HTA has given advice against this criterion.*	**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's 'The quality and safety of organs intended for transplantation' document states that donor and organ characterisation information will be stored for thirty years. Forms used to record information about transplant activity have this requirement printed on them. *The HTA has given advice against this criterion.*	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Living donor and organ characterisation tests are performed at the establishment's laboratories. Their accreditation status was verified from the CPA website and a copy of the relevant accreditation was exhibited.. Histopathology on abnormalities found on a kidney from a deceased donor is usually performed at the donor hospital, but may be performed at the establishment, if required.	**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. In living donor cases, the donor and recipient are discussed at multidisciplinary team meetings prior to retrieval. Procurement and transplantation procedures are usually performed sequentially, enabling the retrieving and implanting surgeons to confer prior to implantation. A recipient coordinator (during working hours) or a specific Transplant Ward nurse (at other times) receives notification from NHSBT of an offer of a deceased donor kidney for a named adult recipient. They print out core donor data from NHSBT's Electronic Offering System (EOS) and phone the on-call surgeon with this information. The surgeon's decision to accept or decline the offer based on the core donor data, or to request additional information from NHSBT, is recorded on the 'Kidney offer form'. This procedure is set out in the establishment's 'The quality and safety of organs intended for transplantation' document. A consultant paediatric nephrologist receives notification directly from NHSBT of an offer of a deceased donor kidney for a named paediatric recipient. They review core donor data on EOS and discuss the offer with a consultant surgeon. This procedure is set out in the 'Paediatric kidney offer' document. *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. A consultant surgeon seeks a living donor's consent for procurement of a kidney, and also their instruction for its fate should it be deemed untransplantable into the intended recipient. The consent form is reviewed by the retrieving surgeon during the pre-operative surgical pause. For deceased UK organ donors, consent or authorisation is sought by a SN-OD under NHSBT's licence.	**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 Trust 'Medical devices policy' states that the Trust must purchase medical devices which conform with legislative requirements and cites the Medicines and Healthcare products Regulatory Agency (MHRA) 'Managing Medical Devices' – DB2006(05) document.	**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 at the Trust central sterilisation unit at Royal Victoria Hospital. There is a Trust 'Decontamination of reusable invasive medical devices' policy. Accreditation certification was exhibited during the audit.	**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. Living donors can spend up to five days in hospital after procurement. The donor visits the hospital two weeks after the procedure for the wound to be inspected, with a surgical follow-up appointment after six weeks. Check-ups take place annually thereafter at the hospital or through the donor's medical practitioner. The discharge letter sent to the donor's medical practitioner advises them to inform the establishment without delay if a donor presents with a condition which may be of relevance to the health of the recipient. A donor can phone a donor coordinator, at any time, if they experience discomfort or any other difficulty following procurement.	**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. Perfusion fluid batch numbers and expiry dates are recorded on HTA A and B forms, and on the operation consumables record which is kept with the patient's notes. An audit of records for three transplant procedures verified that perfusion fluid details had been recorded on the HTA A and B forms and the operation consumables record.	**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. Kidneys are delivered in standard organ boxes by an NHSBT-commissioned courier to the Transplant Ward at City Hospital. The organ is kept in a secure room on the ward. The date and time of receipt, and the checks of slush-ice level, security tag and documentation are noted by a nurse on the 'Kidney receiving form'. The slush-ice level may be topped up if considered necessary. As a safeguard, should documentation accompanying an organ be inadvertently misplaced, a sticker bearing the donor ID number and the staff member who checked it, is affixed to the organ box and also recorded in the 'Kidney chain of custody record book'. A surgeon collects the kidney from the secure room to take it to theatre. Organs to be implanted at the Hospital for Sick Children are delivered initially to City Hospital, receipted as described in the paragraph above, and transported from there by a specified taxi firm. Kidneys procured from living donors at City Hospital are accompanied in transit by a surgeon. A deceased donor kidney arriving at City Hospital outside normal working hours may travel unaccompanied. A kidney may be transported from City Hospital to the UK mainland in cases of non-directed (altruistic) donation, or where a deceased donor kidney is rejected upon receipt at the establishment. If so, a specified company arranges charter flights. In such cases, a kidney is packed in a standard NHSBT organ box which is labelled according to the instructions provided, with the date and time of transportation noted on the 'Kidney despatch form'. Procedures, and forms used to record receipt, checking and distribution, are described in the establishment's 'The quality and safety of organs intended for transplantation' document. *The HTA has given advice against this criterion.*	**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. Minutes of Trust meetings where the requirements were discussed with transport providers were reviewed at 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 implanting surgeon checks donor and organ characterisation information prior to implantation. The checks are recorded on the 'Implanting surgeon's pre-transplant checklist', which is filed with the recipient's notes. This procedure is described in the establishment's 'The quality and safety of organs intended for transplantation' document.	**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. Checks on the ice-slush level and security tag are recorded by a nurse upon arrival of the kidney on the Transplant Ward on the 'Kidney receiving form'. Such checks also take place when a kidney is delivered to the Hospital for Sick Children.	**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 risk-benefit analysis is documented in a recipient's notes by the implanting surgeon, should any donor information specified in Annex A of the Directive be unavailable.	**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. Completed HTA A and B forms are sent to NHSBT by a recipient coordinator via a secure e-mail address within two working days of the transplant procedure, as described in the establishment's 'The quality and safety of organs intended for transplantation'.	**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. Recipients and living donors are traceable in records by their full name, hospital number and date of birth. A deceased donor is traceable by their NHSBT donor number, which is to be found on EOS and 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 receipt of a kidney onto the Transplant Ward at City Hospital are recorded on the 'Kidney receiving form'. The date and time of transportation of a kidney from City Hospital to the Hospital for Sick Children, or from City Hospital to another centre on the UK mainland, are recorded on the 'Kidney despatch form'. All forms state that these are to be kept for thirty years. *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. There is a Trust-wide 'Procedure for reporting serious adverse incidents' policy and an online system for reporting incidents internally. The establishment has adapted NHSBT's standard operating procedure (SOP) SOP3888/1 for notifying NHSBT of a serious adverse event or adverse reaction (SAEAR). In practice, a surgeon will notify NHSBT of a suspected SAEAR. All staff are aware of the 24-hour reporting requirement.	**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 TP5.*	**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. Healthcare professionals involved with transplantation are required to be registered with the appropriate regulatory body, and undertake continuing professional development to maintain their registration. Training records for transplant coordinators, demonstrating attendance at mandatory Trust training sessions, were reviewed. Consultant surgeons have an annual appraisal with the Medical Director. Transplantation is overseen by consultant-level staff. The establishment has adopted, and adapted, NOP005 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation' into the overarching policy document.	**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.	CT3	The HTA advises the establishment to include a question on the living donor health screening questionnaire about recent periods of overseas travel, to identify whether any additional donor virology testing is necessary.
2.	CT4, TC3	The establishment's 'The quality and safety of organs intended for transplantation' document states that traceability records will be retained for thirty years, and relevant forms also state this requirement. There is ongoing discussion within the Trust on how, in practice, this requirement will be met. The HTA advises the establishment to continue such discussion and to agree

		promptly on how this requirement will be met.
3.	CT6, TP1	The establishment has identified several minor amendments to be made to its 'The quality and safety of organs intended for transplantation' document at its next review, to more closely reflect all local practice. The HTA endorses this commitment to quality improvement, and advises on the following amendments to this document: • Incorporating: o the existing SOPs for receipt of an offer from NHSBT of a deceased donor kidney for a paediatric recipient, and the actions to take in case of a positive immunological cross-match between donor and recipient; o NHSBT's instruction sheet for packaging of a kidney, which is available in operating theatres at both hospital sites; • changing reference to 'double-bagging' of a kidney, described on page 20 and in Appendix Six, to 'triple bagging', in line with current practice; • stating what donor and organ characterisation information accompany an altruistic donor kidney sent to another centre for implantation, and the timeframe and method to do so. The establishment is further advised to consider splitting the document into a shorter policy statement, with stand-alone SOPs for specific processes. This may make it simpler to include other existing procedural documents and flowcharts, and to make minor amendments, such as those points noted above.

Concluding comments

The establishment has met all applicable assessment criteria. Several areas of strength were identified. The transplant team is a cohesive unit, with good lines of communication throughout. The establishment has created detailed checklists to record the pathway of an organ from its receipt onwards.

As examples of good practice:

- the establishment has agreed a method with NHSBT to return HTA A and B forms via secure e-mail, and a 'read receipt' is requested to confirm successful delivery;
- laminated sheets with photographic instructions for re-packaging of a kidney for transportation are available in theatres;
- there are plans to audit annually all completed forms used to record the receipt or transfer of an organ;
- theatre staff have attended internal 'EUODD Awareness' presentations, introducing the legislative requirements and local protocols developed to meet them, and their understanding has been tested through a questionnaire;
- the surgeon's decision on acceptance or rejection of the offer of an organ is formally recorded on a 'Kidney offer form'.

The HTA has given advice to the establishment regarding the donor health screening questionnaire, retention of traceability records and further improving 'The quality and safety of organs intended for transplantation' document.

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

Report sent for factual accuracy: 05 November 2013

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

Final report issued: 27 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.