Site visit audit report on compliance with HTA requirements

University Hospitals Coventry and Warwickshire NHS Trust

HTA licensing number 40039

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

28 February 2013

Summary of Audit findings

Although the HTA found that University Hospitals Coventry and Warwickshire NHS Trust (the establishment) had met the majority of the assessment criteria, minor shortfalls were found in relation to the absence of documented operating procedures for verification of donor and organ characterisation information for deceased donors, return of HTA A and B forms to NHSBT, and for packaging and transportation of organs. The discharge letter sent to the donor's medical practitioner does not make reference to serious adverse event or adverse reaction reporting.

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, R, P, T**

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	**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 Coventry and Warwickshire NHS Trust is a single-organ centre (kidneys). All transplantation activity takes place at University Hospital, Coventry and involves adult patients only; there is no paediatric service. Approximately 60 transplants are performed each year, with the majority involving live, directed, donors with the remainder coming from deceased donors.

Tissue typing and cross-matching are performed on behalf of the establishment by an NHS Blood and Transplant (NHSBT) histocompatibilty and immunogenetics (H&I) laboratory, based in Birmingham. The Trust does not provide services to the National Organ Retrieval Service (NORS).

An action plan was issued to the establishment with its continuous licence in December 2012, due to the absence of a documented procedure for reporting serious adverse events and reactions to NHSBT (assessment criteria S2). Progress against this shortfall is discussed further against assessment criteria S2.

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 is applicable for living donors. Mandatory donor and organ characterisation information are collected according to the Work up of Live Kidney Donors clinical operating procedure, and are recorded in the donor's medical notes.	**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. The histopathological examination of a nodule found on a kidney from a deceased donor would be performed at the retrieval centre, with the results being forwarded by NHSBT Duty Office to the Trust. The Trust would, as required, perform any additional histopathology at its own laboratory.	**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 Trust retains all patient records for a period of thirty years.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Certification verifying the full CPA accreditation status of the NHSBT laboratory which performs H&I testing for the Trust was reviewed during the audit. The full accreditation status of the Trust's laboratories was verified with the CPA website.	**None**

CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is almost met. The on-call transplant coordinator will receive a phone call from NHSBT Duty Office when a deceased donor kidney is offered to a named recipient, and is provided with a donor reference number. The transplant coordinator logs onto NHSBT's Electronic Offering System (EOS), transcribes by hand the donor and organ characterisation data onto the Kidney Offer form, and will relay this information by phone to the implanting surgeon who may, on the basis of this information, provisionally accept the organ being offered. When the organ is received, the implanting surgeon will review the HTA A form accompanying it and if they consider it necessary, may refer to EOS. This process is well established and understood by all staff involved, but it is not set out in a documented procedure. Characterisation information for living donors is gathered according to the Work up of Live Kidney Donors' clinical operating procedure, and is recorded in the donors medical notes.	**Minor**

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. Consent for procurement is sought from living donors by a consultant surgeon.	**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. Staff confirmed that materials and equipment supplied to the Trust must meet the requirements of the Medical Devices Regulations, although this is not formally documented in a procurement policy.	**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 used in retrieval are sterilised at the Trust's central sterilisation and decontamination unit (CSDU), whose accreditation certification was reviewed following 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 almost met. Living donors have appointments scheduled at the Trust three weeks, six weeks and six months following their discharge, with annual checks thereafter, in accordance with the Live Kidney Donor Follow–up clinical operating procedure. Donors who live more remotely from the establishment may, if they prefer, receive follow up medical checks at a local hospital or GP practice. Donors returning overseas may receive their follow up checks through a nominated physician, or hospital, in their country of origin. Staff described that donors are also welcome to contact the Trust at any time if they experience any problems. The discharge letter sent to the donor's medical practitioner does not state that, if the donor experiences any serious adverse event or adverse reaction following donation, for example the development of a malignancy, then the establishment must be notified.	**Minor**

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 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 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 manufacturer are recorded on the HTA A and B forms, and on the Perfusion Fluid Record kept in the patient's notes. An audit of donor and recipient notes for a live, directed donation and the donor's notes for an altruistic donation found no anomalies. *The HTA has given advice against this criterion.*	**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 almost met. The establishment may occasionally make arrangements to transport a kidney procured from an altruistic donor to another centre for its implantation or, more rarely, if a deceased donor kidney is declined upon receipt and is re-offered into the national pool. In such cases, the organ is perfused and packaged by the surgeon. The establishment uses an NHSBT organ box which is labelled according to the accompanying instructions, and the HTA A form accompanies the organ. The organ is delivered to the implanting centre by an NHSBT-commissioned courier. The packaging of the organ is recorded by the establishment on the Kidney Transfer form. This transportation process is not described in a documented procedure. *The HTA has given advice against this criterion.*	**Minor**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses kidney boxes that are supplied by NHSBT.	**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 almost met. Refer to criterion TP1.	**Minor**

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 almost met. Refer to criterion TP1.	**Minor**
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. The NHSBT-commissioned courier will report any serious adverse event or adverse reaction to NHSBT.	**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 almost met. For deceased donor kidneys, donor information is verified prior to implantation by the surgeon using the HTA A form and, if necessary, EOS. Refer also to criterion CT6.	**Minor**
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. These are verified by a senior nurse receiving an organ into theatre and recorded on the Kidney Acceptance Form.	**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. In the unlikely situation that incomplete information is available about a donor, the surgeon will discuss with the recipient and with the renal physician whether to proceed to implant the organ. This risk assessment is documented in the patient's 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 almost met. Transplant coordinators will complete and return HTA A and B forms to NHSBT, and are fully aware of the requirement to do this within seven days. However, this requirement is not described in a documented procedure.	**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. Living donors and recipients are identified in documentation by their 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. The establishment records the receipt and distribution of organs, respectively, on the Kidney Acceptance and Kidney Transfer forms. These forms are retained by the Trust for thirty years.	**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. Serious adverse events and adverse reactions (SAEARs) are reported and investigated internally according to a Trust protocol.	**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 almost met. An action plan was issued to the establishment with its continuous licence in December 2012, as there was no documented procedure for reporting SAEARs to NHSBT. The closure date for this action was April 2013. The establishment will be adopting NHSBT's operating procedure SOP 3888/1 for reporting SAEARs. Surgeons have already been informed verbally of the requirement and would, in practice, make a notification of a SAEAR to NHSBT. This assessment criterion will be considered to be fully met when the Trust incident reporting policy has been updated to state this reporting requirement.	**Minor**
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 NHSBT-commissioned courier will report a SAEAR to NHSBT. H&I testing is performed by an NHSBT laboratory.	**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 personnel are registered with the appropriate professional regulatory body, and will undertake continuing professional development through seminars and training courses. All new staff will receive a two-day corporate induction before starting at the Trust, which is supplemented by a local induction programme when they commence their duties. Transplant surgeons, nephrologists and specialist registrars are invited to attend regular seminars on transplant-related topics.	**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 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. Transplantation activity is overseen by a team of consultant surgeons.	**None**

Advice

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

No.	Assessment Criterion	Advice
1	P3, TP1	The establishment is advised that if a deceased donor kidney that it has received is declined and is re-offered into the national pool, then the manufacturer and batch number of any perfusion fluids used for re-perfusion should be forwarded with the organ to its onward destination. The establishment may wish to use the HTA A form to record this information, should there be sufficient space to do this, or alternatively use the Kidney Transfer Record form to record this information, and send this with the organ.

Concluding comments

The auditors were impressed by the dedication, communication and team-working of the staff involved in transplantation work at the Trust. Systems and processes are well-embedded and mature. The work-up and follow-up of living donors are set out in detailed clinical operating procedures and there are clear and simple to use forms to record information about living donors, and the receipt and distribution of organs. The establishment has expressed a firm commitment to adopt and, where necessary, adapt to meet local practices, relevant National Operating Procedures (NOPs) in order to address the shortfalls.

There are a number of areas of practice that require improvement, including some minor shortfalls. The HTA has given advice to the establishment with respect to recording of perfusion fluids.

The HTA requires that the establishment addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the audit.

Report sent for factual accuracy: 2 April 2013

Report returned with comments: 25 April 2013

Final report issued: 26 April 2013

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the organisation has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Audit Report.

Date: 29 July 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.