Site visit audit report on compliance with HTA requirements

University Hospitals of Leicester NHS Trust

HTA licensing number 40054

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

29 January 2013

Summary of Audit findings

The HTA found that University Hospitals of Leicester NHS Trust (the establishment) had met the majority of the HTA assessment criteria.

The establishment was found to have met the majority of assessment criteria, but some shortfalls were found, in relation to documentation of standard operating procedures governing the licensed activities. The establishment has implemented the National Operating Procedures (NOP) but, in relation to some assessment criteria the procedures being followed were not accurately reflected in the procedural documentation.

The establishment had carried out a gap analysis in the run up to the audit date and had identified that some procedural documentation needed further adaptation.

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.

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Licensable activities carried out by the establishment – Procurement activities

Organ type	Kidney
Adult deceased	**P, T**
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, I**

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

Background to the establishment and description of inspection activities undertaken

Transplant activities at University Hospitals of Leicester NHS Trust take place at the Transplant Unit of Leicester General Hospital. The establishment is a single organ centre dealing only with kidney transplant.

The establishment deals with only adult patients and does not retrieve from deceased donors, but carries out retrieval from living, related and unrelated, donors.

Transplantation of kidneys into adult recipients is also carried out.

Living kidney donors are characterised at the establishment, with testing being carried out by the hospital laboratories, which are CPA accredited, and retrieval and implantation takes place at this site.

The transplantation unit is staffed by a small, close knit team and all surgical activity is consultant led, either as principal surgeon, or assisting specialist trainee registrars.

The unit carries out between 90 to 100 transplants per annum, split approximately equally between transplant of cadaveric kidneys and living, related and unrelated, transplantation.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of shortfall
Donor Characterisation and Organ Characterisation		
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.	The establishment is not responsible for obtaining information relating to a deceased donor. This is 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.	In relation to living donors this criterion is fully met as the mandatory, and where required, additional donor information is collected as part of living donor work up. In relation to cadaveric kidney work, this criterion is fully met as any additional characterisation, in the form of histopathological examination, can be carried out on site and reported prior to implantation.	**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. Reference is made to CT2.	**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 relevant NOP has been adopted by the establishment and there is a Trust Records Retention Policy governing the retention of all information for the relevant period. The HTA has provided advice relating to this criterion.	**None**

CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The establishment's laboratory is CPA accredited and documentation confirming this was exhibited to the HTA 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 almost met. In relation to living transplant work where both retrieval and implantation are carried out at the establishment, the same surgical team is involved in planning for and carrying out both operations and has full access to all relevant information in advance of the implantation operation. In relation to living transplant work where the retrieval operation takes place elsewhere, the implanting surgeon is provided with comprehensive donor patient records including information on donor and organ characterisation. In relation to cadaveric kidney implantation work, a member of the surgical team takes the call from the SN-OD and is therefore informed with regard to donor and organ characterisation in advance of the decision to accept a kidney for a recipient at the centre. The establishment has adapted the relevant NOP but this does not fully reflect the differences in procedure pertaining to that detailed above. The NOP needs to be further adapted to fully reflect the procedures carried out.	**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. The surgical staff involved in the procurement are involved in consenting the living donor. Consent is checked during the "surgical pause" in advance of the retrieval operation commencing.	**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 relevant NOP has been adapted and there is a Trust Medical Devices Policy which details that all material and equipment procured by the Trust meets the requirements of the Medical Devices Regulations 2002.	**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. Sterile services are provided to the establishment by an external company. The appropriate documentation confirming compliance with national legislative requirements relating to sterilisation 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 are followed up either at the establishment, at neighbouring hospitals within the Trust or by arrangement with the patient's general medical practitioner (GP). In the latter case the patient is provided with a laminated card advising the GP of the follow up tests required. Follow up appointments are initially scheduled six monthly or annually and there is a procedure in place for chasing up information on living donors from GPs where required. The HTA has provided advice in relation to 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. 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 R2.	**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. Examples of HTA A and B forms were exhibited during the audit, confirming that batch numbers of perfusion fluids used are recorded as required.	**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 has adapted the relevant NOP but this does not fully reflect the procedures which are carried out where kidneys from living donors are transported to other centres or where a cadaveric kidney has been received at the establishment and the decision is made to re-offer it. The NOP needs to be further adapted to reflect local practice. This minor shortfall may be addressed together with the shortfall relating to TP3 and TP4 below in that all relate to adaptation of the same NOP.	**Minor**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses kidney boxes supplied by NHSBT.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labeled with the information specified in paragraph 8(b) (i) to (iv) of the SI, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is almost met. Preparation of organs for transport may take place in the operating theatre, for living retrieval work, or within the laboratory, if a cadaveric kidney is being re-offered. The relevant NOP has been adopted by the establishment but does not fully reflect the local practice and is not specific enough to provide guidance to staff unfamiliar with the practice. The NOP needs to be amended to address these matters. This minor shortfall may be addressed together with the shortfall relating to TP1 and TP4 in that all relate to adaptation of the same NOP.	**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. This criterion only applies to the establishment in relation to living retrievals where the recipient is at another centre or where cadaveric kidneys are being re-offered. The relevant NOP has been adopted but does not fully reflect local practice as the procedures relating to transfer of reports to receiving establishments differs in each case. The NOP does not provide sufficient information to guide staff unfamiliar with the process. The NOP needs to be amended to address these matters. This minor shortfall may be addressed in concert with the shortfall relating to TP1 and TP3 above in that all relate to adaptation of the same NOP.	**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 establishment uses a specialist courier firm, with significant experience in transporting organs for transplantation for the transport of organs for transplant. The relevant contractual documentation, driver's handbooks and instruction sheets were exhibited to the HTA 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. In relation to living kidney transplant, where the retrieval and implantation operations are both carried out at the establishment, the surgical staff are involved in both operations and have access to all identity and other information. Where implant of a living donor kidney, retrieved at another centre, is carried out, the relevant information is provided well in advance of the implantation operation. Surgical staff involved in the implantation operation for cadaveric kidneys obtain the required information direct from SNODs. The donor identity and all relevant information is verified in advance of anaesthetising the recipient. The relevant NOP has been adopted for use by the establishment.	**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 condition of any organ received by the establishment is verified by trained surgical staff and accompanying documentation reviewed to ascertain that the preservation and transport conditions specified have been complied with.	**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. The establishment advised that, where the implanting surgeon has discussed a risk/benefit analysis with the recipient, the risks, benefits, considerations and decisions are transcribed into the patient notes. An example of this was exhibited to the HTA during the audit	**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 relevant NOP has been adopted by the establishment. Examples of HTA A and B forms were exhibited as during the audit and the HTA reviewed information confirming compliance with the requirement to return within 7 days.	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. All donors and recipients are identified by at least three identifiers and all organs are allocated unique identifying numbers.	**None**
TC3) A record (date and time) of the transportation of organs arriving at/or leaving the establishment is kept for 30 years as part of the traceability information.	This assessment criterion is partially met. Receipt of organs into the establishment is to the renal surgical ward, with different staff involved dependant on whether this is within or outside working hours. In either event, delivery is not recorded, other than by signing the courier's delivery paperwork, this not being retained by the establishment. Where cadaveric kidneys are re-offered and sent from the laboratory at the establishment, dispatch is recorded on the laboratory systems. Dispatch of living donor kidneys is not recorded at the establishment, other than by signing the courier's dispatch paperwork, this not being retained by the establishment. The establishment is required to put in place a procedure and related documentation allowing the date and time of receipt or dispatch of organs to be recorded. Alongside this, the records retention policy will need to be amended to ensure that this traceability data is kept for the required period of 30 years.	**Minor**

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 adopted the relevant NHSBT incident reporting procedure. Incidents will be reported, either to the consultant surgeon or service manager for onward reporting to NHSBT.	**None**
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. 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 laboratory facilities used by the establishment are based on site within the same hospital and fall under the same governance procedures. The service agreement put in place by the courier company involved in transporting organs details that any incident is reported immediately. The handbook provided to drivers also clarifies responsibility and timescales for reporting any incident involving the transport of organs.	**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. Examples of training and qualification documents were exhibited during the audit. Nursing staff undergo regular competency assessments and all staff have annual appraisals. The competence of surgical staff is assessed by the Clinical Business Unit management during the appraisal process, and also by regular review of morbidity and mortality rates in relation to patient treatments.	**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. All medical, nursing and laboratory staff are required to undergo continuous professional development, with access to internal and external training courses as required to meet the requirements of their professional bodies.	**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 service is consultant led, with the consultant surgeon overseeing all aspects of the licensed activities. The relevant NOP has been adopted by the establishment.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT4	The HTA advises the establishment to review the Records Retention Policy to ensure that reference to records being kept for three years is a typographical error as records must be maintained for 30 years.
2.	CT4, TC3	The HTA advises the establishment to consider implementing a system to mark or otherwise identify patient and other records relating to transplant patients and delivery and dispatch of organs, in order that the medical records unit are fully aware of the need for these to be retained for the required period of 30 years.
3.	R4	The HTA advises the establishment to consider reviewing letters provided to GPs carrying out follow up assessments of living donors to remind them of the need to report anything which could be a serious adverse event or reaction, and to provide relevant contact details.
4.	CT4, I1, TC1, GN3	The HTA advises the establishment to review the NOPs which have been adopted to ensure that, where required, they are amended to take into account local variation in practice.

Concluding comments

The HTA audit team would like to acknowledge the courtesy shown by the staff at University Hospitals of Leicester NHS Trust. All staff involved in the audit were open and constructive during discussions, providing the audit team with a comprehensive overview of activities carried out and fully explaining procedures and processes.

The audit team saw a number of examples of good practice. Transplant services are provided by a small, close-knit team of experienced staff who take a multi-disciplinary approach to the activities carried out and there is obvious good communication in all areas.

Any testing required as part of donor or organ characterisation is carried out at an on-site laboratory, which helps to ensure good communication.

The service is consultant led and the consultant surgeon is involved in all surgical transplant procedures, either as principal or assisting surgeon or when overseeing surgical procedures carried out by specialist trainees.

As living donor transplant cases make up a substantial proportion of the transplant operations carried out, the establishment has established a system whereby donors are provided with a laminated wallet card which provides their GPs or doctors in other hospitals with an aide-memoire of tests which are required as part of living donor follow up.

The establishment is involved in various research studies relating to transplant activity in an effort to improve the suitability of the processes involved in order to aid successful functioning of transplanted organs

There are a number of areas of practice that require improvement, including five minor shortfalls (three of which may be addressed together). The HTA has given advice to the establishment with respect to some further review of governance documentation, marking of files to aid the medical records department with regard to storage requirements, and the format of letters provided to GPs carrying out follow up assessments.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent for factual accuracy: 15 February 2013

Report returned with comments: 11 March 2013

Final report issued: 15 March 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: 17 June 2013

Appendix: Classification of the level of shortfall (HA)

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 recipient patient or to a living donor,
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 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 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 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 inspection.
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 inspection 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 inspection 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.