Site visit audit report on compliance with HTA requirements

Sheffield Teaching Hospitals NHS Foundation Trust

HTA licensing number 40034

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

13 June 2013

Summary of Audit findings

Sheffield Teaching Hospitals NHS Foundation 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)	**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**

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

Sheffield Teaching Hospitals NHS Foundation Trust (the establishment) carries out deceased and living donor adult kidney transplants within the renal unit at Northern General Hospital. The establishment carries out approximately 60 transplants annually, of these 40 being transplants of cadaveric donor kidneys, the remainder being living donor kidney transplants, primarily directed donations. No paediatric cases are carried out.

The service provided is consultant led, with four consultant transplant surgeons, two specialist grade doctors and one clinical fellow involved in the transplant activity. One of the consultant surgeons undertakes all living donor kidney retrievals. The establishment does not supply staff to a National Organ Retrieval Service team.

Offers of deceased donor kidneys are received directly by the on-call transplant surgeon who has access to the mobile NHS Blood and Transplant Electronic Offering System (EOS) and who makes the decision whether to accept the organ being offered.

If the offer is accepted, the surgeon contacts the recipient coordinator who arranges transport by the Trust's contracted transport provider from the donor hospital to the establishment and subsequently prints off the full EOS record for review by the implanting surgeon.

A service level agreement with the transport provider details what procedures the driver must follow at the donor hospital and also when delivering the organ to the renal ward at the establishment. This procedure is supported by checklists which must be completed and signed by the driver and staff, recording time and date of handover and confirming the checks carried out on transport box integrity, identification, labelling, security tag numbers and slush ice levels.

On receipt at the establishment, the kidney transport box is accepted by staff working to a documented procedure and is transferred to a secure locked side room where ward staff follow standard operating procedures to check documentation and maintain slush ice levels as necessary. Lymph, spleen and blood samples are removed from the transport box and the transport company driver transfers these to a nearby NHSBT CPA accredited Histocompatibility and Immunogenetics (H & I) laboratory in order that relevant blood tests and cross-matching can be carried out.

Subsequently, one of the surgeons who will carry out the implantation takes the organ to theatre where initial back bench preparation and re-perfusion is carried out and, in the usual circumstance where the recipient is not yet in theatre, the organ is repackaged following a defined procedure and transferred back to the ward for secure storage pending transplant. Details of date and time of each handover are recorded on checklists and signed by the staff involved.

If the organ is found to be unsuitable for transplant when initially examined by the surgeon, staff follow documented procedures governing transfer to another establishment for transplant, use for research, or disposal, with details being recorded as appropriate on various checklists and record forms.

The procedures followed where the kidney is from a living donor at the establishment are similar.

Potential living donors go through a defined donor work-up, with two formal assessment visits where relevant social and medical histories are taken and various clinical tests carried out.

In advance of related, directed transplant operations, donors and recipients attend an education visit where they are provided with information on the practicalities of organ donation, risks and benefits and where they have the opportunity to meet with other donors and recipients who have already been through the transplant process.

Living donor and organ characterisation information is passed to the implanting surgeon during multidisciplinary team meetings and the implanting surgeon has access to patient medical records.

During retrieval of a kidney from a living donor, the implanting surgeon is called to theatre and takes responsibility for packaging the retrieved organ, using the documented packaging and labelling procedure, NHSBT transport boxes and materials, and the packaged organ is transferred to the secure storage room adjacent to the ward.

Ward staff follow procedures similar to those used on receipt of a deceased donor kidney. Similar checklists are used to record time of transfer to and from storage and maintenance of slush ice levels.

When the recipient has been anaesthetised, the implanting surgical team complete a modified World Health Organisation (WHO) surgical safety checklist during the surgical pause, and the implanting surgeon confirms that they have reviewed the donor and organ characterisation, confirmed details of consent and has recorded any risk/benefit decisions in writing in the patient notes.

Following completion of the transplant, recipients are provided with information regarding post discharge recovery, their medication and lifestyle factors which may influence the success of the transplant.

Living kidney donors are followed up by the establishment at one week, six weeks, six months and then annually, post-transplant. Where living donors are not local to the area, they are offered the opportunity to be followed up by their general medical practitioner or at a hospital renal unit local to them.

This audit comprised a visual inspection following the organ pathway, discussions with surgical and nursing staff, transplant co-ordinators, transplant and clinical practitioners and a transport driver, together with a review of documented procedures, checklists and record forms.

Three sets of patient notes for related, directed transplants (donor and recipient) were reviewed together with related documentation to determine recording of consent, donor and organ characterisation results, and traceability information relating to transportation.

Two sets of patient notes and related documents for recipients of deceased donor kidneys were similarly reviewed. No anomalies were found.

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 is applicable for living donors. Living donor co-ordinators collect the information specified in Part A of the Annex to the Directive as part of donor work-up during initial telephone conversations and then at donor assessment meetings, following a documented procedural flow-path. Relevant information is recorded on checklists and record forms within patient files.	**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.	For deceased donor kidneys, any further information is obtained by request made to the SN-OD at the donor hospital. For living donors, the information is collected as detailed in 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.	The requirement to hold various types of information for the period of 30 years is included within relevant Standard Operating Procedures. The renal unit retains control of all transplant related patient files and related documentation, stored within the unit and not transferred to the hospital's medical records department.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	The establishment uses a local NHSBT H & I laboratory, which is both CPA and EFI accredited. Confirmation of accreditation 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.	For deceased donor kidney transplant offers, the on-call transplant surgeon receives donor and organ characterisation information by accessing EOS or by telephone conversation with the NHSBT duty office or donor hospital SN-OD. Where the on-call surgeon is not the implanting surgeon, this information is then passed to the implanting surgeon. The full EOS information is subsequently printed off and retained. In living donor kidney transplants, donor and organ characterisation information is provided to the implanting surgeon during multidisciplinary team meetings and by accessing patient notes. Local procedure NOP 001 *"Donor and Organ Characterisation, Acceptance and Allocation"* requires the implanting surgeon to ensure that they have reviewed donor and organ characterisation. The surgical safety checklist, which is completed at the surgical pause, requires the implanting surgeon to confirm that they have reviewed donor and organ characterisation.	**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.	The establishment retrieves kidneys from adult living donors and the surgical safety checklist requires the implanting surgeon to confirm that consent has been verified in advance of the 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.	The Trust has a Medical Equipment Management Group and policies in place which reference national NHS and MHRA guidance on management of medical devices and equipment, requiring that equipment procured and used within the Trust meets the requirements of the Medical Devices Regulations.	**None**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	The establishment uses an external sterile services supplier. Copies of their SOPs and a certificate confirming compliance with relevant standards were exhibited to the HTA 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.	The establishment has a documented procedure, SOP 1217 *"Living donor follow up post transplantation"* governing the frequency of follow up visits, tests to be carried out, and information to be supplied where follow up is carried out elsewhere.	**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.	The Trust has a Medical Equipment Management Group and policies in place which reference national NHS and MHRA guidance on management of medical devices and equipment, requiring that equipment procured and used within the Trust meets the requirements of the Medical Devices Regulations.	**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.	Reference is made to assessment criterion R3. The establishment uses LifePort machines to aid with preservation of kidneys where the cold ischaemic time is lengthy or where they have been procured from Donation after Cardiac Death donors. Staff are provided with a documented work instruction detailing how these machines are cleaned and sterilised.	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	The requirement to ensure details of perfusion fluids coming into contact with the organ are entered onto HTA A and B forms is detailed in NOP001 *"Donor and Organ Characterisation, Acceptance and Allocation"* as the responsibility of the implanting surgeon. Checklists used to record details of back bench organ preparation, packaging and labelling, require staff to record details of batch numbers and expiry dates of perfusion fluids used.	**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.	SOP 1112/2 *"Packaging and labelling of organs in living donation"* details how living donor kidneys are to be packed, transported and stored pending use in implantation. In relation to deceased donor organs, where these are transferred to other centres after having been found unsuitable for transplant at the establishment, SOP 1 *"Notification of a proposed deceased renal transplant"* details the steps staff must follow to repackage, label and arrange transport of the kidney to another establishment.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	The establishment uses only NHSBT approved transport boxes and packing materials.	**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.	SOP 1112/2 (as detailed in TP1) and SOP 1213 *"Procedure to follow when a kidney is not suitable for transplant and is already on the ward or in theatre"* provide staff with guidance on how labelling is to be carried out for subsequent transfer of the organ elsewhere.	**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.	Reference is made to TP3. The procedures detailed therein govern how donor and organisation characterisation accompanies the organ.	**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.	The establishment has a service level agreement in place with its contracted transport provider and the requirement to report serious adverse events, as well as the method for doing so, is detailed within it. The H & I laboratory used by the establishment has systems in place to advise of serious adverse events, required as part of its CPA accreditation.	**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.	NOP001 *"Donor and Organ Characterisation, Acceptance and Allocation"* governs the verification of identity of the donor and collection of donor and organ characterization prior to implant, and the WHO surgical safety checklist, completed during the surgical pause, records that the implanting surgeon has carried this out.	**None**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	NOP001 *"Donor and Organ Characterisation, Acceptance and Allocation"* requires the implanting surgeon to verify compliance with conditions of transport prior to implant, and the surgical safety checklist, completed during the surgical pause, records that this has been carried out.	**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.	The requirement to record risk/benefit analysis is contained within various SOPs used by staff at the establishment and the WHO surgical safety checklist requires the implanting surgeon to confirm that they have recorded any risk benefit analysis in the recipient patient 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.	NOP001 *"Donor and Organ Characterisation, Acceptance and Allocation"* requires the implanting surgeon to complete the HTA A and B forms and return these to NHSBT within 7 days. The forms are collated by the transplant unit secretary, who checks that all relevant information has been completed before posting the forms to NHSBT by recorded delivery.	**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.	The establishment uses NHSBT donor numbers, living donor and recipient hospital numbers, dates of birth and NHS numbers and HTA A and B form numbers, as appropriate, to maintain traceability	**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.	Reference is made to assessment criterion CT4	**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.	The establishment has adapted NHSBT SOP 3888/1 and integrated this with its local procedure *"Reporting an Organ Donation or Transplant Incident to NHSBT"* This governs internal and external reporting and management of any incidents and details the timescales to be met.	**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.	Reference is made 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.	The establishment has a service level agreement in place with its contracted transport provider and the requirement to report serious adverse events, as well as the method for doing so, is detailed therein. The H & I laboratory used by the establishment has systems in place to advise of serious adverse events, required as part of its CPA accreditation.	**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.	The Trust has procedures in place to ensure that transplant surgery is carried out only by suitably qualified or trained surgeons and this is evidenced by results of peer review, procedural log books and review of morbidity and mortality rates. Medical and nursing staff require to have the appropriate qualifications or training as required by job descriptions and person specifications.	**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.	The Trust has procedures in place to update mandatory training as well as to allow staff to complete any CPD training required to maintain professional registration.	**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.	Transplant activity is consultant led. The establishment has adapted National Operating Procedure NOP005 *"Activities under the Guidance of a Registered Medical Practitioner"* to reflect local practice and procedures.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT4, TC3	The establishment is advised, in the event that pressure on space available for storage of records results in records being stored outside the renal unit, to amend the Trust records retention policy to provide that relevant records are retained for 30 years and to ensure that such records are marked to prevent earlier destruction.
2.	CT6	The establishment is advised to reflect the current practice whereby the on-call surgeon relays information relating to an organ offer to the implanting surgeon (where the on-call surgeon is not the implanting surgeon) within relevant SOP documentation.
3.	R4	The establishment is advised to consider whether, when living donors are not to be followed up at the establishment or another renal unit within the UK, the referral letter provided to the organisation which will carry out the follow up should emphasise the need to be vigilant regarding the reporting of serious adverse reactions which may be relevant to the organ recipient.

Concluding comments

The HTA saw various examples of good practice at the establishment. There appears to be a very close working relationship between all staff within the unit.

The establishment has chosen to standardise the practice for temporary storage of cadaveric and living kidneys pending implantation in order that staff follow the same procedures in each circumstance, minimising the risk of any error in storage procedures.

The organ pathway has been analysed in order to draft record forms and checklists providing a comprehensive timeline and audit trail relating to the receipt of organs on the ward and their passage through the establishment. Procedures have been well considered and, where organs are deemed not suitable for transplant, staff are provided with comprehensive guidance on how to deal with the organ for transfer elsewhere for transplant, research or disposal.

The establishment has worked closely with its transport provider to agree the terms of a service level agreement and has integrated the documentation and checklists used by transport drivers with those used by staff receiving organs or sending them elsewhere for transplant, disposal or use for research.

The WHO surgical safety checklist has been amended to reflect the terms of the operating procedure requiring the implanting surgeon to verify the completion of various checks prior to implant, including the recording in writing of any risk/benefit analysis and review of donor and organ characterisation.

Potential living donors are provided with comprehensive information regarding the donation process, including a flowchart detailing all stages of the donation procedure. Those patients undergoing related, directed, transplant operations attend an “education meeting” where comprehensive information is provided to them and they have the opportunity to discuss the transplant procedure, in the absence of establishment staff, with other pairs of donors and recipients who have previously undertaken the procedure.

Before being discharged, transplant recipients are provided with guidance on health and other issues to help them ensure a healthy lifestyle following transplant and as part of discharge procedures take a quiz on post-transplant lifestyle changes and other matters.

The establishment has documented living donor follow up procedures and has put systems in place to allow follow up local to the donor in order to minimise the risk of failed clinic attendance, also having procedures in place to chase up any living donors who do fail to attend for follow up.

The HTA has given advice to the establishment with respect to storage of records, procedures relating to transfer of information between surgical staff and follow up referral letters.

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

Report sent for factual accuracy: 1 July 2013

Report returned with comments: 1 July 2013

Final report issued: 2 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.