Site visit audit report on compliance with HTA requirements

University Hospital of South Manchester NHS Foundation Trust

HTA licensing number 40053

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 Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

10 – 11 May 2017

Summary of Audit findings

The University Hospital of South Manchester NHS Foundation Trust (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment mainly with respect to procedural documentation. The procedural documents which are in place at the establishment cover the areas required by the Regulations, however, in some instances the information is spread across multiple documents. The establishment has produced a transplant protocol which contains descriptions of the procedures for many parts of the transplant process, for example, evaluating an organ offer, acceptance or rejection criteria for organs and donors, and retrieval procedures. The establishment indicates that in time, it wishes to have this transplant protocol as a stand alone procedural document covering all aspects of the transplant process. As a result, advice has been given to the establishment so that the elements required by the Regulations are contained within the transplant protocol.

Particular examples of 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	Heart	Lung
Adult deceased	**DC, OC, P, R**	**DC, OC, P, 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	Heart	Lung
Adult deceased	**OC, P, T, I**	**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

The University Hospital of South Manchester NHS Foundation Trust (the establishment) has been licensed by the HTA since December 2012 under the Quality and Safety of Organs

Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. The establishment undertakes heart, lung and combined heart and lung transplants and also participates in National Organ Retrieval Service (NORS) activity through which it retrieves hearts and lungs from deceased donors. The establishment undertook 28 heart transplants, 22 single lung transplants, 11 double lung transplants and 1 heart/lung transplant during the previous financial year.

The establishment stores equipment and consumables for use in NORS retrievals in dedicated areas within the theatre complex and on the intensive cardiac care unit (ICCU). Retrieval kits are re-packed upon the return of the NORS team. Staff have checklists to follow to ensure that all of the necessary equipment is included in the kits. Chilled and frozen perfusion fluids are stored in a fridge and freezer within the theatre complex and on the ICCU respectively. The fridges and freezer have their temperatures monitored daily as part of the establishment's critical equipment checks. A stock of perfusion fluid is kept in theatres within a locked store cupboard; advice has been given to the establishment regarding monitoring the temperature of the store cupboard (see advice item 8).

During the audit, documentation demonstrating that the establishment's sterile services provider met the requirements of the assessment criteria was reviewed. In addition to the Trust's main sterile services documentation, procedures for decontamination and sterilisation of bronchoscopes and ultrasound equipment were also reviewed. Additionally staff explained the off-site cleaning procedures for this equipment following organ retrievals before the equipment is returned to the establishment for full decontamination and sterilisation.

National operating procedure 004 (NOP004) has been adopted by the establishment which mandates that all equipment used in retrieval and transplantation must meet the requirements of the medical devices regulations. The establishment also has a 'Management of Medical Devices' policy which sets out the requirements for establishment staff when purchasing medical devices. In addition, the establishment's Head of Purchasing provided confirmation to the audit team that all equipment purchased by the Trust is compliant with the medical devices regulations.

All establishment staff working under the licence have been appropriately trained. Examples of competency based assessments and records of training were reviewed during the audit. Establishment staff undertaking additional activities such as use of bronchoscopes have received specific training for these activities and training certificates covering the use of bronchoscopes were seen during the audit. Surgical and perfusionist staff at the establishment have been undergoing training in the use of normothermic perfusion equipment. This has involved visiting the equipment's manufacturer for detailed training followed by undertaking retrievals observed by an external competent clinician.

All staff are subject to annual personal development reviews. Nursing staff are reviewed through their line management structure, retrieval fellows and junior medical staff are reviewed by senior medical staff and consultant surgical staff are reviewed by the establishment's Clinical Director. All mandatory training and appraisals of establishment staff are managed through an electronic system which reminds staff when mandatory training and appraisals need to be undertaken.

During the audit, certification from the establishment's internal and external laboratories used in organ and donor characterisation assessments were reviewed, and demonstrated that they had current Clinical Pathology Accreditation (CPA), United Kingdom Accreditation Service (UKAS) or European Federation of Immunogenetics (EFI) accreditation.

Transplant

An offer of an organ/organs is received by the recipient coordinator who uses the donor identification details to access and review the Electronic Offering System (EOS) to gather further key donor and organ characterisation information. Donor and organ characterisation information is recorded onto a donor offer form by the recipient coordinator and reviewed by the on-call transplant fellow. If the organ and donor are suitable the consultant transplant surgeon is contacted who also reviews the offer and relevant details. If the offer is suitable then it is accepted by the consultant transplant surgeon.

Hearts are offered to specific recipients however currently, when lungs are offered, the establishment reviews the recipients on the waiting list and select the most appropriate recipient. The establishment reported that this process will change in the future with lungs also being offered to named recipients.

Once organs have been accepted, the recipient coordinator liaises with other staff at the establishment to check their availability and to arrange intensive care beds. The recipient is called in and receives an X-ray, anaesthetic assessment, has bloods taken for cross matching, and is seen by the transplant surgeon.

The implanting surgeon reviews the donor and organ characterisation information in EOS when they arrive at the establishment and prior to surgery. If any donor or organ characterisation information is not available prior to implantation, or there is any characterisation information which may represent a potential risk to the recipient, details of the information and the surgeon's risk/benefit analysis are discussed with the recipient. This helps to assure the surgeon that the recipient is able to make a fully informed decision on whether to accept the organ. In undertaking the risk/benefit analysis, the implanting surgeon may also consult with other relevant clinical and medical staff to discuss and review the characterisation information with them prior to having the discussion with the recipient. Such risk benefit discussions between the implanting surgeon and the recipient are documented within the recipient's clinical notes. Advice has been given to the establishment regarding including this risk/benefit decision process, and the procedure through which the conversation with the recipient is recorded, within the establishment's documented transplant related procedures (see advice item 6).

Upon arrival of the organ at the establishment the driver, who has access to the establishment via secure swipe card access, takes the organ directly to theatres where they are met by the recipient coordinator. The recipient coordinator records receipt of the organ and opens the organ box to review the accompanying paperwork. The identification and donor details are verified and the hard copy donor blood group report reviewed and cross checked with the information from EOS by two people. While the organ box is open, the recipient coordinator also checks the transport conditions of the organ and verifies that there is no damage to the outside of the box or to the organ transport bags, and that there is sufficient ice covering the organ. Samples arriving with the organs such as sputum (for lungs), donor blood/lymph and spleen tissue for cross matching and recipient bloods are sent to the relevant laboratories.

Following the implantation surgery the recipient coordinator completes the relevant traceability form, the HTA-B form, and returns this to NHSBT by email and hard copy via the postal system.

Deceased organ retrieval

The establishment's NORS team operates for 26 weeks of the year and is on-call every other week. The establishment uses NHSBT's transport provider under NHSBT's contract for the provision of transport services, and does not hold its own contract. The establishment's

NORS team consists of a surgeon, a transplant fellow, a scrub nurse and a transplant nurse specialist.

Potential retrieval calls are received by the transplant coordinator who then alerts the retrieval team. The coordinator prints off the available donor information from EOS and discusses the case with the retrieving surgeon. Surgical equipment, organ boxes, perfusion fluids and ice are collected and checked against the retrieval checklist. Bronchoscopes, ultrasound equipment and drugs used during retrieval are also collected.

Upon arrival at the donor hospital, the lead retrieval surgeon meets with the specialist nurse for organ donation (SNOD) and checks the donor name, date of birth, blood group, x-rays, echo results, computerised tomography scans, donor virology results, brain stem testing results, coroner's documents and donor consent. The retrieval team aims to arrive at the donor hospital before the abdominal team so that any additional donor characterisation assessments, for example a bronchoscopy and transeosophogeal echocardiogram, can be carried out.

Throughout the travel time of the team to the donor hospital, during the retrieval surgery and following retrieval, the NORS team communicate with recipient centres and NHSBT as necessary so that all relevant teams are aware of the estimated arrival time of the organs at the recipient centres. In addition, the retrieving surgeon contacts the implanting surgeon directly to discuss organ and donor status.

The retrieving surgeon packs the organ according to the national NORS standards which is then placed into the transport box with the relevant traceability paperwork and tissues for typing. The transport driver then collects the organ and transports it to the relevant recipient centre.

The establishment's NORS team has recently been approved to undertake DCD (deceased donors following cirulcatory death) heart retrievals which incorporate the use of a normothermic perfusion device during retrieval and transport. DCD heart retrieval is only undertaken by the establishment's NORS team when it is a local retrieval and where the retrieved organ will be implanted at the establishment. Relevant checklists and documents relating to the use of the perfusion device are contained on a tablet computer and can therefore be accessed easily as required during retrieval. During DCD heart retrievals, the NORS team also includes a perfusionist who has been trained in the use of the perfusion equipment.

Audit of clinical notes

During the audit, a review of recipient clinical notes and associated donor files was undertaken by the audit team. One set of records each relating to a heart, single lung and double lung transplant were reviewed. In each case consent, traceability forms containing details of perfusion fluid (HTA-A and HTA-B), the establishment's transplant assessment, donor information record, communications log and transplant information (containing details of arrival time) forms were reviewed. Other documents including blood serological microbiological testing results, record of EOS, hard copy blood group form and sputum microbiology results (for lung transplants) were also reviewed.Details such as donor ID, microbiological testing results and donor blood group were also cross checked between all of the documents. No anomalies were identified during the audit.

Compliance with HTA assessment criteria

All applicable HTA assessment criteria have been assessed as fully met.

Advice

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

No.	Assessment Criterion	Advice
1.	CT6	The establishment is advised to describe the review of EOS which is undertaken by the implanting surgeon prior to transplant within the establishment's transplant protocol. Although this check is contained within NOP006 which the establishment has adopted, the bespoke transplant protocol for lungs and hearts that is being developed by the establishment should include this review of characterisation information so that it fully reflects the establishment's processes. The establishment may wish to consider adding some of the detail from NOP006 into the transplant protocol. In addition, the establishment should consider recording that this review of the characterisation information has been undertaken by the implanting surgeon. The establishment may wish to consider recording the review on the donor information form, which is used at the establishment, to record other transplant activities.
2.	R2 & P1	NOP004 has been adopted by the establishment which states that all devices used on organ retrieval and implantation meet the requirements of the medical devices regulations. In addition, during the audit an email from the head of purchasing confirming that only equipment that meets the requirements of the medical devices regulations was also reviewed. The establishment's Trust's management of medical devices policy is currently under review and the establishment is advised to consider including in this policy a statement clarifying that all devices purchased by the Trust for use in transplantation meet the requirements of the medical devices regulations.
3.	TP1 & TP2 & TP3	The establishment has adopted NOP003 and operates to the NORS standards regarding the packing of retrieved organs and the labelling of the transport box. The establishment is advised to include details of the packing procedure for organs, and the details of how the transport box must be labelled, within the establishment's transplant protocol. In addition, the establishment is advised to include details of the procedure to seal the organ transport box prior to its departure. Specifically, the use of sealing tape to secure the lid of the box should be included within the documented procedure describing the packing of organs and preparation for transport.
4.	I1	Upon receipt of the donor organ at the establishment, a two person verification of the traceability documentation and donor blood group against the details obtained from EOS is undertaken. The establishment is advised to include details of this verification procedure within the transplant protocol document.
5.	I2	Following transport, the establishment checks the integrity of the organ packaging and that there is sufficient ice remaining upon opening the organ transport box in theatre. The establishment is advised to include details of these checks on the conditions of preservation within the transplant protocol document.

No.	Assessment Criterion	Advice
6.	I3	If any donor or organ characterisation information is not available prior to implantation, or there is any characterisation information which may represent a potential risk to the recipient, details of the information and the surgeon's risk/benefit analysis are discussed with the recipient. This helps to assure the surgeon that the recipient is able to make a fully informed decision on whether to accept the organ. The establishment is advised to include the process for undertaking such risk/benefit analysis and recording the outcome of both the analysis and discussions with the recipient in the recipient's clinical notes within its documented procedures.
7.	TC1	The establishment has adopted NOP006 which stipulates that HTA-A and HTA-B traceability forms are returned to NHSBT within seven days of retrieval/implantation. However, the procedure has not been amended to include details of who at the establishment is responsible for their return. The establishment is advised to update NOP006 or to include the details of the procedure whereby traceability forms are returned to NHSBT within the establishment's transplant protocol.
8.	General	A bulk store of perfusion fluid and sodium chloride solution delivered from the Trust's pharmacy department is kept in a locked cupboard within the establishment's theatre complex. The temperature of the storage cupboard is not monitored in the same way as other storage areas at the establishment such as fridges and freezers. The establishment is advised to monitor the temperature of the storage cupboard to assure itself that the storage temperature does not exceed the temperature limits defined by the manufacturer.

Concluding comments

Areas of good practice were observed during the audit, some examples of these are included below.

When the establishment changed from holding its own dedicated contract for transporting organs to joining the NHSBT held central transport contract, the establishment undertook a piece of work to help train the new drivers. The establishment gave all drivers access to the establishment through its secure swipe card system so that drivers can bring the organ box straight to theatres. The establishment also gave the new drivers training as to the most appropriate place to park so that they were close to theatres as opposed to parking at the hospital's main entrance. These measures have helped to smooth the transition between the two transport contracts and resulted in all drivers visiting the establishment knowing where to go. This in turn helps to minimise transport and handover times of the organ.

The establishment also has good systems for training and developing staff, and sharing learning within the transplant service. The establishment undertakes three study days per year during which staff involved in transplantation present to intensive care unit and other hospital staff. Included in the continuous sharing of learning program are visits from patients who received their transplants at the establishment so that they can share stories of their experiences.

The HTA has given advice to the establishment mainly with respect to procedural documentation. The procedural documents which are in place at the establishment cover the areas required by the Regulations however in some instances, the information is spread across multiple documents. The establishment has produced a transplant protocol which contains descriptions of the procedures for many parts of the transplant process, for example, evaluating an organ offer, acceptance or rejection criteria for organs and donors, and some retrieval procedures. The establishment indicates that in time, it wishes to have this transplant protocol as a stand alone procedural document covering all aspects of the transplant process, As a result, advice has been given to the establishment so that the elements required by the Regulations are contained within the transplant protocol.

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

Report sent for factual accuracy: 9 June 2017

Report returned with comments: 16 June 2017

Final report issued: 10 July 2017

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.

Compliance with HTA assessment criteria

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.
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.
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.
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.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA or UKAS accreditation.
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.

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.
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.
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
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.
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.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.
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.
TP2) The organ shipping container is suitable for transport of the specified organ.
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.
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.
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.
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.
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.

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.
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.
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
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.
Serious adverse events and adverse 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.
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.
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.
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.
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.
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.