Site visit audit report on compliance with HTA requirements

Central Manchester University Hospitals NHS Foundation Trust

HTA licensing number 40043

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 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.

14-15 December 2016

Summary of Audit findings

Central Manchester University Hospitals NHS Foundation Trust (the establishment) was found to have met all assessment criteria.

The establishment undertook a total of 328 transplants, which included 271 kidney only transplants into adult recipients, paediatric transplants, pancreas transplants, and simultaneous kidney pancreas transplants.

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, as amended by the the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 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 licenses 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 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. This is an exception-based report: only those criteria that have been assessed as not met are included. 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

Donor	Kidney	Pancreas	Liver
Adult - deceased	**OC, R, P, T**	**OC, R, P, T**	**OC, R, P, T**
Adult – living	**DC, OC, R, P, T**		
Paediatric - deceased	**OC, R, P, T**	**OC, R, P, T**	**OC, R, P, T**

Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)

Licensable activities carried out by the establishment – Transplant activities

Recipient	Kidney	Pancreas
Adult	**OC, P, T, I**	**OC, P, T, I**
Paediatric	**OC, P, T, I**	

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

Background to the establishment and description of audit activities undertaken

Central Manchester University Hospitals NHS Foundation Trust has been licensed by the HTA since August 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. Licensable activities are undertaken at the Manchester Royal Infirmary (MRI) and the Royal Manchester Children's Hospital.

The transplant ward, theatres where transplants take place, and the Histocompatibility and Immunogenetics (H&I) Laboratory are located together on the second floor at the MRI.

Kidneys and pancreas from deceased donors are implanted into adults (at MRI) and paediatric recipients (at the Royal Manchester Children's Hospital). Kidneys are also retrieved from living adult donors for implantation into adult and paediatric recipients. Transplants at MRI take place in a dedicated theatre to enable the large number of transplants taking place at this establishment.

Retrieval of Abdominal Organs from Deceased donors

Surgeons based at MRI are commissioned by NHSBT as part of the National Organ Retrieval Service (NORS) to retrieve abdominal organs from deceased adult and paediatric donors. On average, this NORS team attends around five donor hospitals every week and shares a one week on, one week off rota along with the NORS team from Leeds General Hospital.

The team prepares and stores retrieval kits and organ boxes for liver, pancreas and kidneys in a dedicated NORS room which has secure keypad access. NHSBT Duty Office mobilises the NORS team by contacting the transport provider which works under a contract with the establishment. The transport provider employs ex-police personnel with advanced driving skills and operates a fleet of ambulances which are satellite tracked, to transport NORS personnel to and from donor hospitals. The transport provider contacts all the members of the NORS team and assists scrub nurses to collect retrieval kits, organ boxes, perfusion fluids, saline and crushed ice from the NORS room before they meet up with rest of the NORS team. The audit team inspected an ambulance on site.

Perfusion fluids are stored in fridges located in the NORS room. The fridges are temperature monitored and stock levels are checked regularly by staff who discard any fluid which is out of date. The NORS team take kidney transporters, which have an inbuilt perfusion system, to the donor hospital if the kidney to be retrieved has been accepted by the MRI for implantation. Transporters are stored in a secure perfusion room where they are kept charged and ready for use.

The team meets the Specialist Nurse-Organ Donation at the donor hospital and checks the death certificate, consent for donation, Coronial permission, if appropriate, and other relevant paperwork. Retrieval takes place after a team brief and once the surgeon confirms the identity of the donor. The surgeon completes an HTA A form which accompanies each organ to the respective transplant centre. The type and batch number of perfusion fluids which come into contact with the organ and any organ damage as well as unusual anatomy is noted on the HTA A form. The surgeon also completes an Operation Note which provides details of each retrieval in accordance with standard MRI procedures. The MRI keeps a log of surgeons that attend each retrieval along with their level of involvement. This log serves as an on-going assessment of competency.

Organs are triple bagged and the organ boxes are tagged and labelled under the supervision of the surgeon, in accordance with the operating procedure published by NHSBT (NOP003). The surgical team liaises with NHSBT Duty Office and implanting surgeons if they have any

concerns about the donor or the quality of the organs retrieved. The surgeon removes a biopsy from kidneys and other organs which are retrieved, if consent is in place, and the donor hospital holds an HTA licence for removal of biopsy as part of the Quality of Organ Donation (QUOD) project. These samples (biopsies, blood, urine) are packaged and transported back to the MRI where they are collected by a member of staff from the H&I Laboratory, processed and send to an HTA licensed establishment which stores QUOD samples.

The establishment's transport provider transports organs which are to be transplanted at the MRI; NHSBT is responsible for transporting organs to other transplant centres.

Deceased Organ Transplants

Kidneys and pancreata are implanted into adult and paediatric recipients at the MRI and the Manchester Royal Children's Hospital respectively.

The on-call recipient co-ordinator (RC) receives an organ offer from NHSBT Duty Office and alerts the on-call surgeon. Staff check the NHSBT Electronic Offering System (EOS) mobile version which provides links to donor information saved on the core donor data form, and the Patient Assessment Form, in order to decide on the suitability of the donor and organ. The H&I Laboratory at the MRI undertake a virtual cross match between the donor and potential recipients after ensuring that the Human Leukocyte Antigen tests for the recipient has been completed within the previous three months. Once the surgeon decides to accept the organ, the RC will liaise with theatres and arranges for the potential recipient and a back-up recipient to be admitted into the hospital.

Clinicians inform potential recipients that immunologically well matched donors could include expanded-criteria donors and high risk donors, before they are placed on the hospital's transplant waiting list. The surgeon provides information on potential risks relating to offered organs and seeks consent from recipients before the transplant takes place. A back up recipient is arranged in the event that the potential recipient decides not to go ahead with the transplant, or if they are found to be unwell when they are admitted into the hospital and are not fit enough for major surgery.

The establishment's transport provider collects and brings organs which have been accepted by the MRI to the transplant ward. Staff on the ward transfer the organ box to the perfusion room which has keypad access. Staff open the box, remove the spleen, lymph nodes and donor blood samples and place them in a fridge in the room. If the kidney is in a transporter, it is stored in the perfusion room until it is ready to be taken to theatres. Staff record details of checks on paperwork, packaging and ice levels on the 'Receiving a Donor Organ checklist'. This form accompanies the box and transporters containing kidneys from the room to the theatres where the transplant takes place. The form is also used to record the release of the organ to other transplant centres.

A member of staff from the H&I laboratory collects the lymph nodes and spleen used for cross matching. Cross matching is undertaken to confirm the donor/recipient match, if a recipient had been recently subjected to any potential sensitising events. Staff also collect QUOD samples which are then sent to an HTA licensed tissue bank where they are stored for research.

A member of the implanting team collects the organ and associated paperwork and takes it to theatres. The implanting surgeon checks the organ and samples around 20ml of the transport fluid for testing. The organ is perfused and the name of the fluid and batch number is recorded on the HTA B form. Surgeons often place kidneys from extended-criteria donors on the kidney transporter before they are transplanted into a recipient. A biopsy is taken from

kidneys from deceased donors before they are implanted; these biopsies are referred to as ‘day zero’ samples.

A surgical pause is observed before any incisions are made. The World Health Organisation checklist is followed to confirm the identity of the recipient and information provided to the surgeon to ensure that they are aware of the latest information on EOS. Completed HTA B forms are scanned and sent to the NHSBT Duty Office. The HTA audit team did not visit the theatre suite at the Children’s Hospital.

Living Donor Kidney Transplants

Potential kidney donors in the local area are assessed at the MRI, Salford Royal Hospital and Royal Preston Hospital. Donors who volunteer are tissue typed in order to determine if they match the recipient before they undergo donor assessment. They complete an initial medical questionnaire which covers travel history and other high risk behaviours before they are subjected to detailed screening procedures. The Living Kidney Donor Co-ordinator interviews them in clinic and arranges for all tests to be carried out. Weekly multidisciplinary team (MDT) meetings attended by nephrologists, surgeons and the rest of the clinical team review and decide on the suitability of each donor. Formal consent is sought from donors and HTA approval is applied for before donation takes place. The donor’s wishes regarding the fate of the kidney if it is not possible to implant it into the named recipient are recorded.

Living donors are reviewed again within eight weeks of donation and mandatory tests are repeated in the event that donation is postponed. Donors and recipients are admitted into the hospital. Donors are re-consented and checks carried out on the identity of the donor before the kidney is retrieved and perfused. The kidney is then transferred to the theatre where the recipient is located and implanted. The surgeon completes the ‘Transplant surgeon donor/recipient checklist’ immediately before each transplant. A letter is sent to the donor’s General Practitioner once the donors are discharged from the MRI. Arrangements are made for annual follow up of donors at clinic.

In the case of paired and pooled kidney donations, NHSBT is responsible for transporting the kidneys to the relevant transplant centres.

Microbiology/Virology Testing

Microbiology services are provided by the Manchester Medical Biology Partnership which is a collaboration between the Trust and Public Health England. The Microbiology and Virology Departments undertake mandatory donor tests for living and deceased donors. The laboratories are accredited by the United Kingdom Accreditation Service. The virology tests are carried out using CE in vitro diagnostic licensed assays on a fully automated immunoassay platform. Results are sent to the respective clinician or to the Specialist Nurse-Organ Donation and NHSBT Duty Office. The microbiology laboratory also carries out tests to detect microorganisms which may be present in organ transport fluid so that recipients can be provided appropriate prophylaxis. The transport fluid (20ml) is centrifuged and then plated onto agar plates which are incubated under conditions which promote the growth of any contaminating bacteria and/or fungi. The audit team were informed that due to lack of standardisation, each transplant centre uses a different protocol and so it was not possible to compare results (sensitivity and specificity) between transplant centres in the UK.

Document Review

A document review was carried out. Clinical notes relating to two deceased donor kidney transplants, a deceased donor simultaneous kidney pancreas transplant and two living donor/recipient kidney transplants (adult and paediatric recipients) were reviewed. Records of consent, mandatory test results, HTA A forms, HTA B forms, details of perfusion fluids used, core donor data forms, donor assessments, checklists detailing checks undertaken before operations and operation notes, as applicable, were reviewed. There were no anomalies.

The accreditation status of the H&I laboratory, the Microbiology Laboratory and the Decontamination Services Department were reviewed and found to be suitable. The Trust wide Medical Devices Management Policy relating to the procurement of medical devices was reviewed; it was noted that the Trust only procured devices which were CE marked. The agreement between the transport provider and the Trust was reviewed; it included the requirement to follow the relevant regulatory requirements and report incidents to the Trust.

Procedural documents such as NOPs linked to local procedures and relevant flow charts such as the Organ Offer pathway, were reviewed. Audit reports and procedures for incident reporting were also reviewed.

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.	CT2	Donors are referred to the MRI from hospitals in the region. The establishment is advised to ensure that the donor assessment forms used by these referring centres are similar to the forms used at the MRI. This will help to ensure that the assessment criteria mirror those used at the MRI and questions such as recent travel are included and assessed. The establishment is advised to consider reviewing the time frame between living donor evaluation and date of donation in order to decide if tests taken during the initial donor evaluation remain valid. The donor may have travelled or been exposed to risks which may mean that test results obtained when the donor was evaluated do not reflect current risks to the recipient.
2.	R1	The establishment is advised to review the disposal form used to document the disposal wishes in the event that a kidney from a living donor cannot be transplanted into a recipient. Donors are expected to mark boxes – 'yes' or 'no' for each option. There was a lack of consistency when completing the form which could create confusion as to the donor's wishes for disposal of the kidney. It is suggested that the form is updated so that donors are provided with one box next to each option and they are instructed to mark the box which is next to their preferred option.
3.	R4	The establishment is advised to include a statement in the discharge letter for living donors which states that the GP or other referral centres such as

No.	Assessment Criterion	Advice
		Royal Preston Hospital and Royal Salford Hospital should inform MRI if, post donation, the donor develops a condition such as a malignancy, which may have implications for the wellbeing of the recipient. This is particularly important in cases of non-directed altruistic or paired and pooled donations where there is no direct relationship between the living donor and the recipient.
4.	GN2	There was a 20% increase in transplantation activities over the previous year. The establishment is advised to risk assess training needs and staff cover in order to ensure that the number of fully trained staff is sufficient to cover transplantation activities and unplanned absences.
5.	N/A	NHSBT recently updated and published version 2 of the National Operating Procedures (NOPs). The establishment is advised to review the updated NOPs in order to implement relevant changes to procedures. The establishment uses a transportable perfusion device when transporting kidneys from donor hospitals for transplantation within MRI. The establishment is advised to consider labelling each perfusion device in order to help identify which device was used in the event that a device fails or when other mechanical issues are identified. Transplant practices are supported by a range of documents including operating procedures, flowcharts, checklists and forms. The establishment is advised to consider implementing a document control system which would help with version control, alert staff when documents have to be reviewed and inform staff, when documents have been updated.

Concluding comments

There are good systems in place for communication between the NORS team, surgeons, theatre nurses, recipient co-ordinators and the transport provider. The handover of information between each shift includes an email detailing offers of organs, key issues, staff availability and activities being undertaken. Theatres, the H&I Laboratory and the transplant ward are located close together which helps to ensure effective formal and informal communication between staff in these areas.

The transport provider sends regular updates to the team about the location and estimated arrival times of team members and organs which are being transported. Ambulances have ports for charging kidney transporters and the transport provider has contingency arrangements in place in the event of adverse weather conditions.

Staff undertake regular checks of the temperature of fridges and freezers where perfusion fluids, samples and saline are stored. Flow charts and notices are displayed in the Perfusion Room and the NORS Room to help remind staff of procedures which should be followed.

The establishment has effective systems in place to record and monitor training of staff. Surgeons log attendance at each retrieval along with their level of involvement which acts as on-going assessment of competency. Every four months the team meets with other transplant teams in the region to discuss incidents and share learning.

The systems of communication, on-going training and shared learning along with the presence of long serving, experienced staff will help to ensure that quality and performance continue to be maintained.

The HTA has given advice to the establishment with respect to reviewing donor assessment forms and disposal forms, discharge letters and the recent versions of the NOPs published by NHSBT.

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

Report sent for factual accuracy: 10 January 2017

Report returned with comments: 25 January 2017

Final report issued: 17 February 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 Regulations..

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