Site visit audit report on compliance with HTA requirements

Plymouth Hospitals NHS Trust

HTA licensing number 40055

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.

21-22 November 2016

Summary of Audit findings

The HTA audited the licensable activities undertaken by Plymouth Hospitals NHS Trust (the establishment) on 21 and 22 November 2016.

Although the HTA found that Plymouth Hospitals NHS Trust had met the majority of the assessment criteria, three shortfalls were found during the audit. The establishment does not have a written procedure which fully describes how organs are packed before they are sent to other centres, checks on the condition of preservation of organs are not undertaken immediately after their arrival at the establishment, and there is no formal procedure describing how donor and organ characterisation information is reviewed immediately before organs are implanted.

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 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	Organ type	Activity
Adult - deceased	**Kidney**	**OC, P,T**
Adult – living	**Kidney**	**DC, OC, R, P, T**

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

Licensable activities carried out by the establishment – Transplant activities

Recipient	Organ type	Activity
Adult	**Kidney**	**OC, P, I, T**

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

Plymouth Hospitals NHS 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 South West Transplant Centre based at Derriford Hospital. Surgeons at the Centre retrieve kidneys from living adult donors and implant kidneys into adult recipients. Staff do not currently retrieve kidneys from deceased donors, although they have done so in the past. The establishment uses proprietary software to record and collate clinical data to monitor transplant patients.

Tissue typing, virtual and wet cross matching takes place at the Histocompatibility and Immunogenetics Laboratory (H&I Lab) which has Clinical Pathology accreditation. Donor virology testing takes place at the Microbiology Laboratory which is accredited by the United Kingdom Accreditation Service and is a regional test centre for deceased and living donors in Plymouth, Exeter, Devon and Cornwall. Both laboratories are located within Derriford Hospital.

The South West Transplant Centre holds regular multidisciplinary team meetings and also holds a 'declined organs' meeting to review organ offers which are declined to assess if the approach to accepting and rejecting organs is appropriate.

The proprietary software used to record clinical information relating to patients on the transplant list, living donors and kidney recipients can be accessed remotely and is used by nephrologists and clinical nurse specialists when considering organ offers.

Perfusion fluids used are stored in a fridge within the theatre suite. Theatre staff are responsible for checking perfusion fluids to ensure that they are within their use-by date and that sufficient stock is available. The establishment does not use hypothermic perfusion devices to perfuse kidneys, though in the past these devices were used to perfuse kidneys obtained from donors after circulatory death.

NHSBT is responsible for making arrangements to transport kidneys to and from Derriford Hospital. Occasionally however, the establishment is responsible for packing of organs into transport boxes when organs from a deceased donor or organs retrieved during paired/pooled living donations are sent on to other transplant centres. Staff attach the new colour coded labels issued by NHSBT to label organ boxes. The colour of the label indicates whether the right or left kidney is being transported; the destination of the organ is noted on the label.

<u>Living Donor Kidney Transplants</u>

The Living Donor Co-ordinator is responsible for liaising with potential living donors. Nephrologists, surgeons and the Living Donor Co-ordinator follow a care pathway which is used to document key discussions including donor and organ evaluation. Printed information is provided to potential donors. Blood typing, tissue typing and cross matching are undertaken to assess compatibility with the recipient. Living donors complete an initial questionnaire which includes questions on social and medical history. The questions cover existing and former medical conditions, use of recreational drugs and behavioural history. Donor virology testing is carried out to determine the suitability of the donor. Scans and screening tests are undertaken in accordance with NHS screening guidelines. Consent is sought from donors only after detailed discussions are held to inform them of the risks related to donation. An HTA Independent Assessor interview takes place once the donor is deemed to be clinically suitable. Donor nephrectomy takes place within a short period of time from the

characterisation assessments in order to minimise the time between tests that have been carried out, and the donation.

In most cases the recipient and the donor are scheduled to be in adjacent theatres to minimise the time interval between retrieval of the kidney from the donor and its implantation into the recipient. The surgical team use the World Health Organisation surgical safety checklist which includes checks on consent, before proceeding to retrieve the kidney from living donors.

Derriford Hospital has a large proportion of non-directed altruistic donors. In many cases, kidneys from non-directed altruistic and paired and pooled donations are transported to other hospitals for implantation. Theatre staff and the surgeon pack the organ and NHSBT makes arrangements to transport the kidney to the recipient centre.

The establishment monitors the health of donors following donation. Initial checks are carried out every few months and this is followed up by annual checks (see advice item 3). Information obtained is recorded in the transplant programme's proprietary information management system.

Deceased Donor Kidney Transplants

Organs are procured from donors by the National Organ Retrieval Service (NORS) teams which work under the licence held by their local transplant centre.

NHSBT Duty Office contacts Recipient Co-ordinators (RC) based at Derriford Hospital to offer kidneys retrieved by NORS teams across the UK to recipients on the waiting list. RCs follow a standard checklist to ensure that they request and review key information on the donor and potential recipients. They access the Electronic Offering System (EOS) to review information on donor and organ characterisation. They also access the proprietary hospital information management system for transplantation, to review information about potential recipients. The RC contacts the on-call nephrologist who reviews the offer and accepts or declines the kidney. On occasion, the nephrologist may contact the on-call surgeon to discuss the offer, if additional considerations have to be taken into account before the kidney is accepted for transplantation.

NHSBT arranges the transport and the RC keeps in contact with NHSBT Duty Office to ensure that they are kept updated on the estimated arrival time of the kidney. The RC monitors EOS so that he/she is aware of any new information which could impact on the quality of the kidney. The H&I Lab performs a virtual cross match. The H&I Lab is aware of recent potential sensitising events as the immune status of potential recipients are monitored every three months and information on sensitising events is sought when potential recipients are contacted and asked to enter hospital.

The organ box containing the kidney arrives at the reception desk of the H&I Lab which is staffed 24 hours. Staff open the box to remove the spleen and lymph nodes in order to perform a wet cross match. Staff then close the box and re-tag it before taking the box to theatres. Staff record the receipt of the kidney box, old and new tag numbers and the time of transfer to the theatres on the 'Kidney Donor-Cross Match details' form. However, staff do not check the ice level within the box or carry out other checks to confirm that transport and storage conditions are appropriate.

Wet cross matches usually take around four to five hours and in almost all cases, a wet cross match is performed before a kidney is implanted into a recipient. There can be a gap of several hours before the on-call transplant surgeon arrives in theatre to check the quality of the organ and undertake back bench work prior to implantation. RCs and theatre staff work

twelve hour shifts starting or ending at 8am. Hence, in many cases there is a handover from one set of staff to another after a kidney has been accepted for transplantation.

The audit team were informed that surgeons checked EOS, or were provided with the latest version of EOS, so that the most up to date information on donor and organ characterisation was reviewed before implantation. However, there is no formal procedure which describes this process.

Microbiology Laboratory at Derriford Hospital

The Microbiology Laboratory receives and tests blood samples from living and deceased donors. The Laboratory performs serology testing for HIV 1/2, Hep B, Hep C, HTLV 1/2, CMV, EBV, Syphilis and Toxoplasma. The laboratory records and reports test results as well as the time of collection of the blood sample. The laboratory participates in external quality assessment schemes and staff follow flow charts and detailed Standard Operating Procedures. Tests for the presence of microorganisms are undertaken on the transplant fluid surrounding the kidneys. If any microorganism is detected the laboratory informs other centres which have received organs from the same donor for implantation via the NHSBT Duty Office.

Document review:

Documents reviewed included minutes of meetings, reports prepared by the Transplant steering group and several sets of clinical notes. They included records relating to a kidney retrieved by the NORS team based at another HTA licensed establishment and two kidney transplants from living donors. Records reviewed included as appropriate, printouts from EOS, consent forms, 'Kidney Donor-Cross Match details' form, and HTA A and HTA B forms which include records of perfusion fluids used.

Staff follow a procedure for reporting incidents to NHSBT; these incidents are also reported and investigated within the Trust.

The HTA audit team reviewed several Trust documents. The Sterilisation and Decontamination Unit at Derriford Hospital is certified under ISO 13485, for cleaning, disinfection, packing and sterilisation of instruments, surgical procedure packs, instrument trays, Endoscopy and supply of sterile theatre and ward packs, patient drapes and hollow ware. The Trust follows the guidance on managing Medical Devices which was published by the Medicines and Healthcare Products Regulatory Authority in 2015. Transplant records are kept for 30 years post transplantation.

Compliance with HTA assessment criteria

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.	There is no formal procedure which fully describes how to pack organs which are sent to other recipient centres for implantation. There are several instances when organs from living donors including paired, pooled and non-directed altruistic donor kidneys, and kidneys from deceased donors, are sent to other centres. In the absence of a formal procedure, there is a risk that organs are not packed in accordance with the latest guidance issued by NHSBT to NORS teams responsible for retrieving and packing abdominal organs – see advice item 5.	**Minor**
Implantation		
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior to proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	There is no formal system to describe the process which ensures that the surgeon is made aware of the latest information on EOS immediately prior to implanting a kidney. Consultant nephrologists are responsible for accepting or declining offers of kidneys from deceased donors. They may consult with a surgeon before accepting or rejecting a kidney. Once a kidney is accepted, the RC is responsible for checking updates in EOS and providing information to the surgeon. The time interval between the offer of an organ and implantation can be at least five hours. Staff handovers can take place during this time period and EOS is likely to be updated. A formal process for checking information in EOS immediately before implantation, and verification of this check would help to ensure that the surgeon is made aware of the most up to date information on donor and organ characterisation – see advice item 6.	**Minor**

Assessment Criteria	Audit findings	Level of Shortfall
Implantation		
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	There is no formal system to review the conditions of preservation and transport. Staff in the H&I Lab record the tag number and other details in the 'Kidney Donor-Cross Match details' form, but do not check and record information such as the integrity of the box and the level of ice within the box. In addition, staff have not been instructed to top up the level of ice in the box, to ensure that the organ is fully covered, as set out in section 8 and section 9 of National Operating Procedures NOP002 and NOP003 respectively, issued by NHSBT in July 2012. There is a risk that there may not be sufficient ice within the box to maintain the quality of the kidney, given that there is a gap of at least five hours from the time that the organ box arrives at the H&I Lab and checks are carried out by the surgeon.	**Minor**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	The Microbiology Laboratory report results of donor testing once all tests in the panel have been finalised; this includes tests which have had to be repeated. The laboratory is advised to consider reporting finalised test results, even if some other tests in the panel are pending. This may enable NHSBT to progress potential donations from deceased donors whilst awaiting finalised test results. Any such changes to the reporting procedure should only be made in consultation with NHSBT.
2.	R2	The establishment follows guidance issued by the Medicines and Healthcare Products Regulatory Agency 'Managing Medical Devices – Guidance for healthcare and social services organisations' published in April 2015. The establishment is advised to include a reference to this document when the Trust's medical devices policy is next updated.
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 centre should inform Derriford Hospital if, post donation, the donor develops a condition such as a malignancy, which may have implications for the wellbeing of the recipient.

No.	Assessment Criterion	Advice
		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 may not be aware of the medical condition of the donor.
4.	P1	Theatre staff undertake daily checks on the fridge where perfusion fluid is stored to ensure sufficient stock is available. The staff are advised to monitor the temperature of the fridge in order to ensure that the fridge temperature meets the manufacturer's guidelines for storage.
5.	TP1	The establishment is advised to draft and implement a formal procedure for packing kidneys which is in accordance with procedure in Section 7 – Abdominal perfusion and preservation protocol for NORS teams in the UK, MPD1043/7, issued by NHSBT on 3 October 2016.
6.	I1	The establishment is advised to draft and implement a formal procedure by which a surgeon is made aware of the latest information on EOS. The process could involve a member of staff printing or emailing a copy of EOS to the surgeon immediately before implantation or the surgeon could log into EOS and view the latest version of EOS.
7.	GN2	The establishment has one Living Donor Co-ordinator. The HTA audit team were informed that there were other members of staff who could take on the role. The establishment is advised to ensure that those members of staff are fully trained and could cover all aspects of the role in order to ensure that there is sufficient cover for unplanned absences.
8.	N/A	The establishment is advised to update the NOPs to include references to all transplant related forms which are in use such as the Donor pathway, the use of the proprietary transplant database and instructions to package the kidneys.

Concluding comments

There are robust systems in place to assess living donors. Clinicians follow a comprehensive living donor care pathway used to document discussions, medical and social history and test results of potential donors. 'Declined organ' meetings are used to help calibrate the level of risk which would be acceptable when receiving offers of kidneys from deceased donors. The H&I Lab and the Microbiology laboratory play a central role in the success of transplants undertaken by the Southwest Transplant team.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the establishment with respect to updating documents, drafting procedures, ensuring there is sufficient cover for the role of living donor co-ordinator, amending the discharge letter relating to living donors and temperature checks on the fridge where perfusion fluid is stored.

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

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

Report sent for factual accuracy: 20 December 2016

Report returned with comments: no comments received

Final report issued:17 February 2017

Completion of corrective and preventative actions (CAPA) plan

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

Date: 1 April 2020

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.