Site visit audit report on compliance with HTA requirements

Barts Health NHS Trust

HTA licensing number 40052

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)**
- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)**

Under the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

16 December 2014

Summary of Audit findings

This was a non-routine site visit audit of Barts Health NHS Trust (the establishment), following a routine site visit audit in 2013, to assess the development of a programme for local retrieval of kidneys from deceased circulatory death (DCD) donors.

The establishment was found to have met all relevant assessment criteria. Advice has been given on strengthening the processes and documentation in place. Some criteria which were assessed as fully met at the routine audit in 2013 were not assessed again, and are omitted from this report.

The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and any requirements imposed by directions made under these Regulations.

The assessment criteria reflect the requirements of the statutory conditions outlined in schedule 1 and the HTA's directions. They are designed to promote the safe use of human organs and ensure traceability is maintained between donor and recipient. The HTA audits establishments it licences against eight groups of assessment criteria:

- Donor characterisation and organ characterisation
- Retrieval of organs for transplantation
- Organ preservation
- Making arrangements to transport an organ
- Implantation
- Traceability
- Serious adverse events and serious adverse reactions
- General (apply to all licences)

Reports of HTA audits are published on the HTA's website.

Throughout the audit process, the HTA assesses the establishment against the assessment criteria. Where the HTA determines that an assessment criteria is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 1: Classification of the level of shortfall). Where HTA assessment criteria are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided in this report.

Licensable activities carried out by the establishment – Procurement activities

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

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

****** *Only criteria relevant to this new procurement activity were assessed at this non-routine site visit audit*

Licensable activities carried out by the establishment – Transplant activities

Organ type	
Adult living	**OC, P, T, I**

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

Background to the establishment and description of audit activities undertaken

Barts Health NHS Trust ('the establishment') is a single-organ transplant centre (kidneys). Transplantation activities take place at Royal London Hospital, and involve adult donors and recipients only. The establishment does not perform paediatric transplants or provide services to the National Organ Retrieval Service (NORS) for deceased donors. A routine HTA site visit audit of this establishment was conducted in January 2013; the audit report is available on HTA's website.

The establishment intends to commence local kidney retrievals from adult deceased circulatory death (DCD) donors. The establishment will be working to the Extended DCD ('eDCD') protocol, developed jointly by NHS Blood and Transplant (NHSBT) and King's Health Partners, to increase the number of transplantable organs available from DCD donors.

Under the eDCD protocol, this establishment's surgeons will retrieve kidneys from DCD donors who are pronounced life extinct between three and twelve hours after withdrawal of life sustaining treatment; retrieval will not proceed if death does not occur within twelve hours of withdrawal of life sustaining treatment.

eDCD kidney retrievals will take place at Royal London Hospital or at King's College Hospital ('KCH'; HTA licensing number 40023), with 12-15 eDCD kidney retrievals anticipated to take place annually across both sites during this pilot phase of the project. There are no plans for eDCD retrieval to take place at other Barts Health NHS Trust sites during the pilot.

NHSBT's Specialist Nurses – Organ Donation (SN-ODs) seek consent from the donor's family for organ retrieval, and will also offer them the option to consent for organ donation under eDCD protocols if death does not occur within three hours of withdrawal of life sustaining treatment. If the donor's family has given consent for eDCD retrieval, the SN-OD informs the establishment's on-call surgeons when the organs are offered on NHSBT's Electronic Offering System (EOS) so they are aware of the possibility.

As per routine national protocols, the NORS team will retrieve the donor's organs if death occurs within three hours of withdrawal of life sustaining treatment, and will leave the hospital if death does not occur in that period. If the donor's family has given consent for eDCD kidney retrieval, the on-call surgeon will arrive to assess this possibility. If the donor dies between three and twelve hours of withdrawal of life sustaining treatment, the eDCD protocol will proceed. Following pronouncement of donor death, the retrieving surgeon will connect the donor's organs to an extracorporeal membrane oxygenation (ECMO) machine for *in situ* perfusion prior to retrieval. Both this establishment and KCH have an ECMO machine available onsite. Kidneys will be placed on Lifeport perfusion machines by the retrieving surgeon. Kidneys will usually be implanted at Royal London Hospital but may also be offered to a small number of other transplant units within the region, to maximise organ usage.

The eDCD protocol document provides detailed information on the seeking of informed consent for eDCD retrieval from the donor's family, steps following standing down of the NORS team and the retrieval, packaging and transportation of organs (refer to advice item 2). The roles of the surgeons, SN-ODs and intensivists are clearly explained within the protocol.

During this non-routine site visit audit the HTA reviewed the new eDCD protocol and met with surgeons who will perform eDCD kidney retrievals. Some assessment criteria that were assessed as fully met at the routine site visit audits of this establishment and of KCH in 2013 were not re-assessed during this audit, and are omitted from this report.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. Mandatory donor and organ characterisation information set out in Part A of the Annex to the Directive is gathered by SN-ODs at the retrieval centres and is available on EOS. *The HTA has given advice against this criterion*	**None**
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.	This criterion is fully met. Any additional characterisation tests, such as histopathology on a nodule found on an organ, will be performed at the retrieval hospital (either Royal London or KCH).	**None**
CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Information about the donor and the retrieval will be recorded on EOS and on the HTA A form. The SN-OD or retrieving surgeon may contact an implanting surgeon directly if, for example, an organ is damaged at retrieval. If an implanting surgeon decides that a kidney isn't suitable to be implanted in the intended recipient, it is not re-offered. *The HTA has given advice against this criterion*	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Retrieval of Organs for transplantation		
R1) Procurement is only carried out after all the requirements relating to consent (or authorisation in Scotland) have been met.	This criterion is fully met. NHSBT will train SN-ODs on seeking consent for eDCD retrieval. SN-ODs will explain to the donor's family the option to consent to donation under the eDCD protocol if donor death does not occur within three hours of life sustaining treatment being withdrawn. The retrieving surgeon reviews the consent form as part of the pre-operative surgical checklist.	**None**

R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. If organs are retrieved at KCH, the surgeon will use KCH's retrieval kits and perfusion fluids. Documented procedures and policies addressing this criterion were reviewed at routine site visit audits of this establishment and of KCH in 2013, and were not reviewed again at this non-routine audit.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. *Refer to assessment criterion R2*	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. The retrieving surgeon will record perfusion fluid details on the HTA A form, which is returned to NHSBT by the SN-OD. *The HTA has given advice against this criterion*	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Making arrangements to transport an organ		
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Under the eDCD protocol, kidneys are placed in Lifeport perfusion machines by the retrieving surgeon. Lifeport machines are CE marked. If the retrieval and implantation centres are different, organs will be transported between the sites by ambulance. This is mentioned in the eDCD protocol. *The HTA has given advice against this criterion*	**None**

TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. *Refer to assessment criterion TP1*	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. *Refer to assessment criterion TP1* *The HTA has given advice against this criterion*	**None**
TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Organ and donor characterisation information is available on EOS. Documented procedures and policies addressing this criterion were reviewed at routine site visit audits of this establishment and of KCH in 2013, and were not reviewed again at this non-routine audit.	**None**
TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.	This criterion is fully met. Transportation of organs will normally be by ambulance.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Implantation		
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Documented procedures addressing this criterion were reviewed at the routine site visit audit of this establishment in 2013; as described in that audit report, the 'Deceased Donor Kidney Pathway' and the HTA A form would be verified during pre-operative surgical checks. *The HTA has given advice against this criterion*	**None**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion is fully met. Data on flow and resistance parameters of kidneys placed on Lifeport machines is available to an implanting surgeon.	**None**

I3) Where any of the information specified in Annex A of the Directive is not available; a risk-benefit analysis is conducted to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.	This criterion is fully met. As noted in the establishment's 2013 audit report, should any of the information specified in Annex A of the Directive be unavailable, the offer of the organ would be refused. Potential recipients will be informed that kidneys can be procured under the eDCD protocol and are consented accordingly. *The HTA has given advice against this criterion*	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Documented procedures addressing this criterion were reviewed at a routine site visit audit of this establishment in 2013, and were not reviewed again at this non-routine audit. The retrieving surgeon will complete the HTA A form, which is returned to NHSBT by the SN-OD.	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. Deceased donors are traceable through their NHSBT donor number, which is on EOS and the HTA A form.	**None**
TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.	This criterion is fully met. If an organ is to be transplanted at another centre, the retrieving surgeon will record the date and time of transportation of the organ from the retrieval centre.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Serious adverse events and reactions (SAEARs) – (*these criteria apply to all licensed activities*)		
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.	This criterion is fully met. Documented procedures addressing this criterion were reviewed at a routine site visit audit of this establishment in 2013, and were not reviewed again at this non-routine audit. Any serious incident at an eDCD retrieval, such as surgical damage to an organ, would be reported to NHSBT by the retrieving surgeon.	**None**
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. *Refer to assessment criterion S1*	**None**
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.	This criterion is fully met. *Refer to assessment criterion S1*	**None**

Assessment Criteria	Audit findings	Level of Shortfall
General – (*these criteria apply to all licensed activities*)		
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.	This criterion is fully met. The eDCD protocol sets out responsibilities of personnel. A core team of consultant transplant surgeons is trained in use of ECMO machines and kidney retrieval from DCD donors. One surgeon's certificate of attendance at a refresher training session on use of Lifeport machines was reviewed at the audit. (NHSBT will train SN-ODs on seeking consent for eDCD organ retrieval).	**None**

GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.	This criterion is fully met. *Refer to assessment criterion GN1*	**None**
GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.	This criterion is fully met. *Refer to assessment criterion GN1*	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2, I1, I3	eDCD retrieval will take place only if donor death occurs within twelve hours of withdrawal of life sustaining treatment, in line with the consent given by the family. The HTA advises that if any new medical or behavioural information becomes available about the donor during that time, for example from their family or their medical practitioner, the implanting surgeon should be informed as soon as possible. This will enable the implanting surgeon to fully inform recipients on the potential risks and benefits of a proposed transplant.
2.	CT6, P3, TP1	The HTA advises the establishment to develop from the eDCD protocol document an operating procedure which could describe, for example: • how a SN-OD or retrieving surgeon could communicate relevant information about the donor or the retrieval to an implanting surgeon; • which perfusion fluid is used for kidneys kept in Lifeport machines; • how kidneys may be transported from a retrieval hospital to an implanting centre, and who will accompany them in transit; Such an operating procedure could also reference the existing policies, operating procedures and flowcharts at this establishment and at KCH.
3.	TP1, TP3	Lifeport machines are not labelled with, for example,'Handle with care' or 'Organ in transit', as required by paragraph 69 of the HTA's 'Guide to quality and safety of organs intended for transplantation – a documentary framework'. The HTA advises the establishment that it can print laminated cards with the required information, and connect these to Lifeport machine handles with cable ties to meet these requirements. http://www.hta.gov.uk/_db/_documents/Organs_Intended_for_Transplantation_-_a_documentary_framework_-_July_2014.pdf

Concluding comments

The establishment has met the criteria assessed at this non-routine site visit audit. eDCD organ retrieval will be conducted by a core team of consultant transplant surgeons who were involved in developing this protocol and hence are familiar with it. Additional SN-OD resource will be made available at Royal London Hospital and KCH to expedite the new activity. Stringent performance indicators and quality audits for the programme have been developed.

The HTA has given advice to the establishment with regard to providing an implanting surgeon with new information which may come to light about the donor's medical or behavioural history, developing an operating procedure for eDCD retrieval based on the eDCD protocol, and labelling of Lifeport machines.

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

Report sent for factual accuracy: 31 December 2014

Report returned with comments: 23 January 2015

Final report issued: 23 January 2015

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.