**Site visit audit report on compliance with HTA requirements**

**St George's University Hospitals NHS Foundation Trust**

**HTA licensing number 40050**

**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.**

**24 January 2017**

## Summary of Audit findings

The HTA audited the licensable activities undertaken by St George's University Hospitals NHS Foundation Trust (the establishment) on 24 January 2017. The establishment was found to have met all assessment criteria.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

## The HTA's regulatory requirements

The HTA shall ensure that licence holders are audited for the purposes of ensuring compliance with the licensing conditions in schedule 1 of The Quality and Safety of Organs Intended for Transplantation Regulations 2012, 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, P, R, 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,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**

St George's 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 St George's Hospital, Tooting. Surgical procedures are carried out by five transplant surgeons who work on a one in five on-call rota. The hospital has moved to a paperless sytem and so all records relating to transplants are scanned and stored in a digital format. Information relating to donors is kept separate from clinical notes and other information about the recipients.

Patients receive information on transplants, and risks and benefits associated with transplanting kidneys from marginal donors, before they are placed on the transplant list. Recently, there has been an increase in the number of pre-emptive transplants, *i.e.* transplants that take place before a patient starts kidney dialysis.

Tissue typing, virtual and wet cross matching takes place at the NHSBT Histocompatibility and Immunogenetics Laboratory (H&I Lab) which has Clinical Pathology accreditation and is located on the St George's Hospital site.

South West London Pathology provides medical microbiology services to support transplant activities. Tests for HIV 1/2, Hep B, Hep C, HTLV 1/2, CMV, EBV, syphilis and *Toxoplasma* are undertaken for living donors. In the case of deceased donations, the laboratory will undertake tests, in addition to those recorded in the Electronic Offering System (EOS), if requested by the surgeon. The laboratory reports test results through an electronic reporting system; the report includes the time of collection of the blood sample. A sample of transport fluid which surrounds kidneys from deceased donors is sent to the microbiology laboratory for analysis. Surgeons will inform NHSBT Duty Office if any microorganism is detected in the transport fluid as it may have implications for recipients of other organs from the same deceased donor.

Perfusion fluids used are stored in a fridge within the theatre suite. Theatre staff are responsible for checking the temperature of the fridge and the stock level of perfusion fluids. Staff check that the fluids in the fridge are within the use-by date. The establishment occasionally uses hypothermic perfusion devices to perfuse kidneys following donation after circulatory death. These devices are kept charged and staff check the devices on a regular basis so that they can be used at short notice.

<u>Deceased Donor Kidney Transplants</u>

NHSBT Duty Office texts on-call junior doctors attached to the transplant service, to offer kidneys retrieved by the National Organ Retrieval Service (NORS) teams. Junior doctors access EOS to review information on donor and organ characterisation. They record information on a 'Kidney Offer' form which acts as an aide memoire when they discuss the case with the consultant surgeon on call and the nephrologist. The junior doctor reviews the medical history of the potential recipient before they accept or decline the offer. Junior doctors continue to monitor EOS so that he/she is aware of any new information which could impact on their assessment of the quality of the kidney.

The transplant team usually requests a sample of the deceased donor's blood from NHSBT as soon as they accept a kidney for transplantation. The blood sample is delivered to the H&I Lab to enable a peripheral blood cross match against serum from the potential recipient. The H&I Lab is aware of recent potential sensitising events as the immune status of potential

recipients is monitored every three months. In addition, the H&I Lab is made aware of sensitising events such as recent blood transfusions when potential recipients are contacted and asked to enter hospital.

NHSBT Duty Office arranges the transport and provides regular updates to the junior doctor on the estimated arrival time of the kidney. The organ box arrives at the hospital and is taken to the side room within theatres where it is kept until the transplant surgeon arrives. Staff record the tag number of the organ box and remove the spleen and lymph nodes used for cross matching. Checks are carried out on the integrity of the box and the level of ice in the box.

Occassionally, if a peripheral blood sample has not been received, the organ box is directed to the H&I Lab where there are procedures in place to re-tag the box, after the spleen and lymph nodes have been removed and the box is sent on to theatres.

When a potential recipient is admitted into hospital, the surgeon or senior registrar is responsible for providing him/her with information about any known risks associated with the donated kidney before consent is sought for transplantation. The transplant team always has access to the emergency theatres and so transplants can be undertaken without delay. The kidney is evaluated by the surgeon who does backbench work and re-perfusion as required. The surgical team team follow the World Health Organisation (WHO) checklist and is made aware of recent updates to EOS. This step is is recorded before surgery commences.

On rare occasions, the kidney is deemed to be unsuitable and declined after it reaches St George's Hospital. NHSBT then fast track the kidney and re-offers it to other transplant centres in the local area. If the fast track offer is accepted, staff at St George's hospital re-pack the kidney in accordance with a documented procedure, so that it can be collected by a courier arranged by NHSBT, and transported to the receiving centre.

There are regular multidisciplinary team meetings including 'declined organs' meetings held every three months, where decisions made to accept or reject organs are reviewed.

Living Donor Kidney Transplants

The Living Donor Co-ordinators provide information to potential donors on the risks associated with being a donor. The co-ordinators arrange for blood and tissue typing of potential donors and cross matching to assess compatibility with the recipient. Nephrologists, surgeons and the Living Donor Co-ordinators follow a care pathway which covers the social and medical history of the potential donor. They ask questions about their sexual history and their use of recreational drugs. Donor virology testing, scans and screening tests are undertaken before formal consent is sought for donation. HTA authorisation is sought and donor nephrectomy takes place within a short period of time, usually within a few months, so as to ensure that all donor characterisation test results remain valid.

The recipient and the donor are scheduled to be in adjacent theatres and WHO surgical safety checklists are completed before knife to skin. If the organ is retrieved for paired/pooled living donations, the surgical team follow the documented procedure for packing the kidney before it is sent on to another transplant centre. NHSBT is responsible for making arrangements to transport the kidney to the recipient centre.

The establishment makes arrangements for on-going monitoring of the donor. A letter is sent to the donor's GP. The centre provides considerable information to the donor regarding the importance of follow up appointments and annual checks.

Document review:

Documents reviewed included minutes of meetings, HTA A and B forms, completed consent forms and records of perfusion fluids used. Several operating procedures, checklists and completed forms used and incidents were reviewed. Notes and forms associated with two deceased donors and two living donors were reviewed. There were no discrepancies.

The HTA audit team reviewed several Trust documents. The Policy for the Management and Use of Medical Devices (issued June 2016) references the Medicines and Healthcare Products Regulatory Authority guidance on managing medical devices (2015). Evidence that the Sterile Services Department is accredited to ISO13485:2012, ISO9001:2008 and compliant to 93/42EEC was reviewed.

## Compliance with HTA assessment criteria

All relevant HTA assessment criteria were met.

## Advice

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

| No. | Assessment Criterion | Advice |
|---|---|---|
| 1. | 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 should inform St George's Hospital if, post donation, the donor develops a medical condition such as a malignancy, which may have implications for the recipient. Whilst staff at St George's Hospital stress the importance of regular follow up to donors, such a statement would increase awareness of the importance of keeping the hospital aware of the medical status of the donor. Around 10% of living donors are from overseas and it is important that the GP in their home country is made aware of the importance of communicating such findings to clinicians at St George's Hospital. |
| 2. | P1 | Theatre 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 of perfusion fluids. During the audit it was noted that there were several days when the temperature of the fridge was not monitored or recorded.<br>*Following the audit the HTA was informed that a new fridge was installed and that a system of daily temperature monitoring has been implemented. Theatre staff will record the temperature of the fridge everyday.* |

## Concluding comments

The transplant service is well led. Multidisciplinary team meetings are held regularly. Junior

doctors, supervised by senior clinicians, are responsible for accepting and rejecting kidneys for transplantation, thus providing on-going development opportunities. There is good communication between the transplant team, H&I Lab and the Microbiology laboratory.

Local Operational Pathways cover key stages of the transplant process. They include the live donor pathway, live kidney donor health questionnaire, live donor follow up, Surgical team pathway for deceased donor organ acceptance, Receipt and dispatch of organs, Kidney dispatch form, WHO time out form where the final check of EOS is noted, and several clinical protocols. These documents are uploaded onto the hospital intranet and are accessible to all clinical staff.

The service is well supported by the Trust. Staff have immediate access to theatres as required and this has helped St George's to have one of the shortest cold ischaemic times in the country for kidneys from deceased donors *i.e.* time interval between retrieval of a kidney and implantation into a recipient.

Regular audits take place including transplant outcomes, review of results of microbial analysis of the transport medium, and audits of completion of transplant records including the time-out form, cold ischaemic time, scanning of operation notes and return of HTA A and B forms to NHSBT. The Renal and Transplantation department has weekly educational training sessions followed by an interactive Journal Club.

The HTA has given advice to the establishment with respect to amending the discharge letter relating to living donors and temperature checks on the fridge where perfusion fluid is stored.

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

**Report sent for factual accuracy: 21 February 2017**

**Report returned with comments: 24 February 2017**

**Final report issued: 21 March 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 |
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| 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. |

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| 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. |

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| 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. |