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

**St George's Healthcare NHS 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 Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012**

**29 August 2013**

**Summary of Audit findings**

St George's Healthcare NHS Trust (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 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, P, T, R** |
| **Adult deceased** | **OC, 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)

### Licensable activities carried out by the establishment – Transplant activities

| Organ type | Kidney |
|---|---|
| **Adult** | **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 Healthcare NHS Trust ('the establishment') is a single-organ centre (kidneys), performing in excess of 100 transplants each year. Transplantation involves adult patients only; there is no paediatric service. The establishment also provides transplant services for renal units at St Helier Hospital (Carshalton) and Royal Sussex County Hospital (Brighton).

Tissue typing and cross-match for patients of the establishment, and of Royal Sussex County Hospital, are carried out by the NHS Blood and Transplant (NHSBT) histocompatibilty and immunogenetics (H&I) laboratory in Tooting. For St Helier Hospital patients, these tests are performed at Guy's and St Thomas' NHS Foundation Trust (HTA licensing number 40029). Other characterisation tests for living donors, and any additional characterisation tests required on kidneys from deceased donors, are performed at the establishment's laboratories as necessary.

The Trust does not provide services to the National Organ Retrieval Service (NORS). Outside of the NORS system the establishment, in a small number of cases each year, may receive direct communication from a Specialist nurse – organ donation (SN-OD) or from NHSBT Duty Office of a potential local kidney-only deceased after circulatory death (DCD) donor or, occasionally, a deceased after brain death (DBD) donor. Contact is made directly to one of the two surgeons who perform deceased donor kidney retrievals. If the offer is provisionally accepted, a local retrieval team comprising two surgeons (one consultant, one junior), a perfusionist and a scrub nurse is mobilised to retrieve the kidneys, for implantation at the establishment. Transportation to and from the donor hospital is by an NHSBT-commissioned courier. Kidneys are normally transported in organ preservation machines, and are always accompanied back to the establishment by the retrieval team. If, upon receipt, the establishment decides not to proceed to implant the kidneys, the kidneys can be re-offered into the national sharing scheme.

During the audit, the auditors followed the pathway of a kidney being received into the establishment, reviewed transplant-related documentation, audited a selection of patient records, and held round-table discussions with surgeons and transplant coordinators.

## Compliance with HTA assessment criteria

| Assessment Criteria | Audit findings | Level of Shortfall |
|---|---|---|
| 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. | This criterion is not applicable.<br>The establishment is not responsible for obtaining information relating to a deceased donor. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence. | **N/A** |
| 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 applicable for living donors.<br>Living donor and organ characterisation information is gathered during work-up in line with the 'Live donor work-up checklist'. | **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.<br>For living donors, any additional donor and organ characterisation tests necessary are carried out by the establishment.<br>For deceased donor kidneys any additional characterisation tests required on a donor or on the kidney are usually performed at the donor hospital. Additional tests on a kidney, such as histopathological examination of a nodule, can also be performed at the establishment as required. | **None** |
| 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. | This criterion is fully met.<br>The Trust Health Records Policy states that transplantation records will be retained for thirty years. | **None** |
| CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation. | This criterion is fully met.<br>The Trust Health Records Policy states that transplantation records will be retained for thirty years. The Clinical Pathology Accreditation (CPA) status of the establishment's microbiology and histopathology laboratories, and of NHSBT Tooting and Guy's and St Thomas' NHS Foundation Trust H&I laboratories, was verified on the CPA's website. | **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.<br><br>Living donor and organ characterisation information is collected during work up in line with the 'Live donor work-up checklist'. Donor work-up and suitability are always discussed at multidisciplinary team meetings. Prior to implantation, the retrieving and implanting surgeons discuss donor and organ characterisation information, and the retrieval procedure.<br><br>Procedures for accepting offers of kidneys from deceased donors are set out in the 'Surgical junior doctor pathway for deceased donor organ acceptance' (for kidneys offered through the national sharing scheme) and the 'Controlled DCD/DBD kidney offer retrieval' procedure. For kidneys offered through the national sharing scheme, notification of a potential offer from either a SN-OD or NHSBT Duty Office is received by an on-call surgical junior doctor, who transcribes donor information from the electronic offering system (EOS) onto the 'Kidney offer' form, and can accept or reject an offer based on that information, or request additional donor characterisation tests. The implanting surgeon verifies the donor information using the HTA A form and, as necessary, EOS and this is recorded on the 'Time out for deceased donor and KSS renal transplants' form.<br><br>The 'Kidney transplantation – theatre pathway, receipt and despatch of organs' document states that a retrieving surgeon must inform the recipient centre, the implanting surgeon and NHSBT Duty Office if a kidney appears sub-optimal, is damaged or has an unexpected abnormality, and to document their concerns on the HTA A form. | **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.<br><br>Consent for procurement from living donors is sought by surgical junior doctors. The donor's instruction for the fate of the kidney, should it be deemed untransplantable into the intended recipient, is also sought.<br><br>For deceased UK donors, consent is sought by a SN-OD under NHSBT's licence. At local DCD retrievals, the retrieving surgeon reviews the consent form during the pre-operative surgical pause, and records this in the donor's notes. | **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.<br>The Trust's Procurement Policy and Clinical Product Management Policy address this criterion. | **None** |
| R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented. | This criterion is fully met.<br>Reusable instruments are sterilised at the Trust's Sterile Services Department (SSD). A letter dated July 2012 from the SSD Manager confirmed the SSD's full compliance with relevant EU requirements, and its ISO13485:2003 and ISO9001:2008 accreditation. | **None** |
| 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. | This criterion is fully met.<br>Donors receive surgical follow-up appointments after two weeks, and at three and six months, either at the establishment or the referring hospital. Subsequent annual follow-up appointments take place at the establishment or referring hospital, or through the donor's medical practitioner.<br>Staff were receptive to advice provided on adding a statement to the discharge letter for the donor's medical practitioner that the establishment should be notified if the donor experiences an adverse effect which may be related to the organ donation, or develops a transmissible infection or malignancy which could impact on the health of the recipient.<br>*The HTA has given advice against this criterion.* | **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.<br>*Refer to assessment criterion R2.* | **None** |
| P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented. | This criterion is fully met.<br>*Refer to assessment criterion R3.* | **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.<br>Perfusion fluid details are recorded on HTA A and B forms, copies of which are kept with the operation notes.<br>An audit of records for three transplant procedures verified that perfusion fluid batch numbers and expiry dates were recorded by the establishment on the HTA A and B forms. | **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.<br>The 'Kidney transplantation – theatre pathway receipt and despatch of organs' and the 'Controlled DCD / DBD kidney offer retrieval' documents describe the procedures for transportation of kidneys to and from the establishment. Organ transportation is carried out by an NHSBT-commissioned courier. Kidneys retrieved from local DCD donors are normally transported in organ preservation machines, which are CE-marked. Kidneys to be implanted at another centre are transported in NHSBT boxes that are packaged and labelled according to the accompanying instructions, and a 'Donor kidney collection form' is completed with the transport details. The HTA A form accompanies the organ in all cases. | **None** |
| TP2) The organ shipping container is suitable for transport of the specified organ. | This criterion is fully met.<br>*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.<br>*Refer to assessment criterion TP1.*<br>*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.<br>*Refer to assessment criterion TP1.* | **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.<br>The NHSBT-commissioned courier is contractually obliged to report a serious adverse event during transport directly to NHSBT. | **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.<br>Donor information is verified prior to implantation by the surgeon using the HTA A form and, as necessary, EOS and is recorded on the 'Time out for deceased donor and KSS renal transplants' form. | **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.<br>The implanting surgeon records their verification of donor information, box tag number and slush-ice level prior to implantation on the 'Time out for deceased donor and KSS renal transplants' form.<br>Kidneys transported in organ preservation machines are accompanied during the journey from the donor hospital by the retrieval team and are taken directly to theatres. | **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.<br>A risk-benefit analysis would be documented in the recipient's operation notes. | **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.<br>The return of HTA A and B forms to NHSBT is recorded using an electronic spreadsheet.<br>While the 'Kidney transplantation – theatre pathway, receipt and despatch of organs' document states the requirement to return HTA A forms for deceased donors to NHSBT within seven days, this requirement is not documented for living donors. This was fed back to the establishment during the audit as an item of advice; staff amended the 'Donor discharge and follow-up for living kidney donors' document on the day to state this requirement. Hence, this has not been included as a separate item of advice on this report. | **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.<br>Deceased donors are identifiable by their NHSBT donor number, which is recorded in EOS and on the HTA A form.<br>Recipients and living donors are identifiable by their name, hospital number and date of birth. | **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.<br>The receipt and despatch of organs is recorded on the appropriate forms, which are kept with the operation notes.<br>The Trust Health Records Policy states that transplantation records will be retained for 30 years. | **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.<br>Serious adverse event and adverse reaction (SAEAR) notifications are managed internally through Datix, and the 'Reporting serious adverse events regarding a donor or transplant recipient' document explains how to report a SAEAR to NHSBT. Staff are fully conversant with the requirement, and procedure, for SAEARs reporting to NHSBT. | **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.<br>*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.<br>The H&I laboratories at NHSBT Tooting and at Guy's and St Thomas' NHS Foundation Trust, have been notified of this requirement. The NHSBT commissioned courier is contractually obliged to report a serious adverse event during transport directly to NHSBT. | **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.<br>Healthcare personnel are registered with the appropriate professional regulatory body, and undertake continuing professional development to maintain their registration. | **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.<br>Training records for transplant coordinators demonstrated their ongoing attendance at training sessions on clinical and non-clinical topics. Surgical junior doctors attending local DCD retrievals receive refresher training on the use of organ preservation machines every month. Surgeons deliver a series of lectures on 'transplant and renal failure surgery' each year. | **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.<br>Transplantation is a consultant-led service. Staff roles and responsibilities are clearly defined in documented procedures. The establishment has adopted National Operating Procedure 005 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation'. | **None** |

### Advice

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

| No. | Assessment Criterion | Advice |
|---|---|---|
| 1. | R4 | The HTA advises the establishment to include a statement in the donor's discharge letter that it should be notified if the donor experiences an adverse effect which may have arisen from the organ donation, or develops a transmissible infection or malignancy which could potentially have an impact on the health of the recipient. |
| 2. | TP3 | The organ preservation machines normally used for transporting kidneys retrieved from local DCD donors have 'L' and 'R' written on them, but are not otherwise labelled, for example with 'Handle with care' or 'Organ in transit'. As the shape of a machine makes it difficult to affix labels to it, the HTA advises that a laminated card, stating the information required by paragraph 68 of the framework document, is tied to the handle of the machine using a cable-tie. |

**Concluding comments**

The establishment has met all applicable assessment criteria. Many aspects of strength were noted. The dedication and professionalism of staff involved with transplantation was apparent to the auditors. There are well-written documented procedures detailing all aspects of the transplantation pathway. Staff responded proactively to advice given at the audit, including revising documented procedures on the day, underlining their commitment to continuous quality improvement. Points of good practice noted include that a donor's consent for re-implantation, disposal or storage for use for research of a kidney which is deemed to be untransplantable, is sought prior to retrieval

The HTA has given advice to the establishment with respect to labeling of organ preservation machines.

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

**Report sent for factual accuracy: 19 September 2013**

**Report returned with comments: 27 September 2013**

**Final report issued: 27 September 2013**

## 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.