Site visit audit report on compliance with HTA requirements

Guy's and St Thomas' NHS Foundation Trust

HTA licensing number 40029

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

23-24 April 2013

Summary of Audit findings

Although the HTA found that Guy's and St Thomas' NHS Foundation Trust (the establishment) had met the majority of the assessment criteria, minor shortfalls were found in relation to an absence of documented procedures for the transportation of organs, and relaying donor and organ characterisation information to an implanting surgeon.

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**

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

Guy's and St Thomas' NHS Foundation Trust (the establishment) carries out kidney and pancreas transplants. These could be simultaneous pancreas-kidney (SPK) or pancreas after kidney (PAK) procedures.

Transplant activity for adult patients takes place at Guy's Hospital. Organs for paediatric recipients are implanted at Evelina Children's Hospital, situated at the St Thomas' Hospital site. Donor and organ characterisation tests, other than those undertaken by NHS Blood and Transplant (NHSBT) for deceased donors, are performed by the establishment's laboratories.

Surgeons hold honorary contracts with Great Ormond Street Hospital (HTA licensing number 40041) and King's College Hospital (HTA licensing number 40023) to implant organs at those establishments under their HTA licences. Surgeons implant kidneys and pancreata at King's during simultaneous liver-kidney or liver-pancreas procedures. Adult live donor kidneys for implantation at Great Ormond Street Hospital are procured at Guy's Hospital. Deceased donor organs to be implanted at Great Ormond Street and King's College Hospitals are delivered first to Guy's Hospital for samples to be removed from the box for tissue typing before being transported onwards. The establishment's Clinical Transplantation Laboratory provides histocompatibility and immunogenetics (H&I) testing services for King's College and Great Ormond Street Hospitals.

The establishment does not routinely provide services to the National Organ Retrieval Service (NORS), although a surgeon may occasionally attend a NORS retrieval from a deceased paediatric donor if requested to do so.

An action plan was issued to the establishment with its continuous licence in December 2012, due to the lack of a documented procedure for reporting serious adverse events and reactions to NHSBT (assessment criteria S2).

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.	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 is applicable for living donors. This criterion is fully met. Mandatory donor and organ characterisation information is logged in the donor's electronic patient record. For overseas donors, any serology tests that were carried out in their country of origin are repeated at the establishment.	**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. For deceased donors, a surgeon may request additional donor or organ characterisation tests to be carried out at the retrieval hospital. Additional tests, such as histopathological examination on a nodule found on an organ, can 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. The Trust 'Heath Records Procedures' policy states that all patient records are to be archived indefinitely in a digital format.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Certification verifying the full CPA accreditation status of the Trust's laboratories was reviewed during the audit.	**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 almost met. For living donors, donor and organ characterisation information collected during work-up is logged in the donor's electronic patient record. An implanting surgeon may attend the retrieval procedure, or speak with the retrieving surgeon prior to implantation. A SN-OD or NHSBT Duty Office will telephone a surgeon directly with notification of the offer of an organ from a deceased donor. The surgeon logs onto NHSBT's Electronic Offering System (EOS) and may provisionally accept an organ on offer based on core donor data in EOS, or may request further tests to be performed on the donor or the organ at the retrieval hospital. The surgeon may also discuss the offer of an organ with a nephrologist. Upon receipt of an accepted organ, the implanting surgeon reviews the HTA A and 'Organ Pathway' forms as part of the pre-operative surgical checklist. These consultant-led processes are well-established, but are not described in a documented procedure.	**Minor**

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. Consent for procurement from living donors is sought by a consultant surgeon. The donor consent form is verified during the pre-operative surgical checklist. Consent for procurement from deceased UK donors is carried out under NHSBT's licence.	**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. The Trust 'Medical Equipment Procurement Protocol' addresses this criterion. A rigorous internal procedure is to be followed if any non-standard medical device is to be purchased.	**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. Reusable instruments are cleaned and sterilised by the Trust's Central Sterilisation Unit (CSU). Evidence of external validation will be submitted to the HTA following the audit.	**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. Donors are seen by a surgeon two weeks after being discharged but may, if needed, be seen prior to that at a Rapid Assessment Unit at the hospital. Donors receive annual health checks thereafter. If a donor returns overseas following their donation, the results of health checks carried out in their home country are sent to the establishment. The donor's discharge letter, which is copied to their medical practitioner, advises that the establishment should be notified if the donor experiences an adverse effect which may be related to the donation.	**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 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. Refer to 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. Perfusion fluid details are recorded on HTA A and B forms and in the patient's operative notes.	**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 almost met. As noted in the Background to this report, surgeons from Guy's transplant organs at three other hospitals within London. In such cases, the organ will either have been procured from a living donor at Guy's or, if the organ was from a deceased donor, it will be delivered firstly to Guy's for tissue samples to be removed for cross-matching before being sent to its destination. Organs procured at Guy's that are to be transported to another hospital are packaged by a surgeon, who seals the box. Transported organs are always accompanied by a member of the transplant team. The date and time of transportation are recorded on the 'Organ Pathway' form which is placed in the transport box. The establishment uses organ boxes supplied by NHSBT, which are labelled according to the instructions provided. Occasionally, a deceased donor organ is not suitable for implantation by the establishment and is reallocated to another centre. In such instances, the organ is transported to its destination by NHSBT-commisioned couriers. Protocols for transporting organs are well-established, but are not described in a documented procedure.	**Minor**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. Refer to 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 criterion TP1.	**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 almost met. As noted in the Background to this report, most organs transported by the establishment will be implanted at another hospital in London by a surgeon from Guy's, who will have reviewed donor information from EOS or, in living donor cases, spoken with the retrieving surgeon. Occasionally, a deceased donor organ which is declined upon receipt at Guy's is re-offered into the national pool for implantation at another hospital. There is no documented procedure explaining how any additional organ characterisation information gathered while the organ is at Guy's will be provided to the recipient centre.	**Minor**
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. The establishment uses a specific taxi company to transport organs to Great Ormond Street Hospital. The organ is always accompanied by a member of the transplant team, who would notify the establishment of a serious adverse event during transportation.	**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. The 'Organ Pathway' and HTA A forms are reviewed by the implanting surgeon as part of the pre-operative surgical checklist. For deceased donors, core donor data from EOS is also reviewed at that time.	**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. The HTA A form and the ice-slush level are checked by a Specialist Registrar when an organ is delivered to Richard Bright Ward by the courier and again when it is received into theatres. The checks are recorded on the 'Organ Pathway' form.	**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. If core data on a deceased donor was unavailable at the time of offering, the organ would be declined.	**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. The procedure for collating and returning HTA A and B forms, and the seven-day requirement for doing so, are described in the 'Admin process for tracking HTA forms' instruction sheet. *The HTA has given advice against this criterion.*	**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 by their NHSBT reference number, which is on EOS and the HTA A form. Recipients and living donors are traceable in hospital records by their name, NHS 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. The date and time of arrival of an organ at Guy's and, where applicable, its transportation to another hospital for implantation, are recorded on the 'Organ Pathway' form.	**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. Clinical incidents are reported within the Trust through Datix. The establishment has adopted NHSBT's standard operating procedure (SOP) 3888/1 for reporting of serious adverse events and adverse reactions, and staff are aware of the reporting requirement.	**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 criterion S1. *The HTA has given advice against this criterion.*	**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 criterion TP5.	**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. Healthcare personnel involved in transplantation are registered with the appropriate professional regulatory body, and will undertake continuing professional development. All new staff receive a two-day Trust induction. New transplant coordinators and surgeons have a structured training pathway, which begins with observation of colleagues and culminates in eventual sign-off of competence.	**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 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. Transplant activity is performed under the guidance of consultant surgeons. The establishment has adopted National Operating Procedure 005 ‘Activities to be performed under the guidance of a registered medical practioner 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.	TC1	The establishment is reminded that HTA A and B forms are to be returned to NHSBT not, as stated in the 'Admin process for tracking HTA forms' instruction sheet, to the HTA. This instruction sheet should also explain how HTA B forms for procedures at Evelina Children's Hospital will be returned to Guy's, and how to proceed if an HTA B form is not received from there promptly.
2.	S2	As surgeons at this establishment perform transplants at several hospitals, and patients come from across a large geographic area of the south of England, the establishment is advised to clearly define in its SAEARs reporting protocol the roles and responsibility of staff for reporting a suspected SAEAR to NHSBT. This will help to ensure that SAEARs notifications are made and followed up in a timely manner.

Concluding comments

The commitment of staff to successful transplant outcomes was very apparent to the audit team. Working practices are effective and are firmly embedded. There were many examples of good practice. The management of records relating to transplantation is to a high standard. Surgeons and transplant coordinators at Guy's have good lines of communication with colleagues in the tissue typing laboratory, and at Evelina Children's Hospital. The use of the 'organ pathway' form which tracks organs from the time the organ enters the hospital through to the tissue typing laboratory and finally to the theatre ensures traceability and helps to strengthen the checking procedure for organs before they are transplanted.

Points of good practice noted include that:

- the recipient of an organ from an overseas donor must confirm before the procedure takes place that the donor will be able to receive their annual health checks in their country of origin;
- surgeons seek a living donor's consent for the re-implantation, disposal or storage for use for research if an organ is deemed to be untransplantable.

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 documented procedures for managing HTA A and B forms, and communication channels if a potential SAR is reported to Evelina Children's Hospital.

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 May 2013

Report returned with comments: No factual accuracy or request for redaction comments were made by the establishment

Final report issued: 10 June 2013

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: 09 November 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 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.