Site visit audit report on compliance with HTA requirements

Great Ormond Street Hospital

HTA licensing number 40041

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

28 November 2013

Summary of Audit findings

Great Ormond Street Hospital (the establishment) was found to have met all assessment criteria. The establishment was part of a pilot audit at the end of 2012. This audit focussed on key areas for improvement identified during the pilot.

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

Adult and paediatric deceased only	
Heart, lung, kidney, liver and pancreas	**R, P, T**
Heart, lung, kidney, liver and pancreas	**R, P, T**

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

Licensable activities carried out by the establishment – Transplant activities

Adult and paediatric	
Heart, lung and kidney	**OC, P, T and 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

Multi-organ transplant activities take place at Great Ormond Street Hospital (GOSH), London. The hospital specialises in providing treatment for children up to 16 years old. The hospital maintains a list of patients requiring transplants as well as specific requirements such as size and matching characteristics. Transplantation of heart, lungs and kidneys takes place at GOSH. Liver transplantation, if required, occurs at another licensed establishment.
The establishment does not routinely supply staff to the National Organ Retrieval Service (NORS).

The hospital has an embedded Specialist Nurse Organ Donation (SN-OD) who undertakes licensable activities under the NHS Blood and Transplant (NHSBT) licence. The donation team and retrieval teams function independently in order to prevent any potential conflict of interest.

Format of audit

The establishment was audited over two days in November 2012 as part of the HTA's pilot audit programme in the organ donation and transplantation sector. A report was written for the establishment, but not published. After the pilot audit, the establishment addressed some shortfalls found following the pilot audit through a corrective and preventive action (CAPA) plan. This routine audit focussed on the actions taken to complete the CAPA plan since the pilot audit. The audit included discussions with staff, review of new documents and patient notes. No anomalies were found in the patient notes. Specialist nurses for both teams keep separate files to maintain information on organ characterisation. Donor information is not held by GOSH, as donor notes are maintained by NHSBT and / or donor hospitals.

This report contains content from the original pilot audit report and information gathered during this routine audit. Since the pilot audit, the establishment has completed all actions identified in the CAPA plan.

The two transplant teams: cardiothoracic team and abdominal, are organised independently of each other and do not share documented procedures. The teams maintain separate documentation to suit their clinical practices.

Cardiothoracic organ pathway:

Most of the cardiothoracic organs received by GOSH are retrieved by the UK NORS teams. The GOSH cardiothoracic surgeons do not participate in the NORS, however, they may occasionally be called upon to assist NORS teams to retrieve cardiothoracic organs from deceased paediatric donors at other hospitals in the UK, if specialist paediatric surgical skills are required. Two or three times a year, cardiothoracic surgeons employed by the establishment are involved in organ retrievals from Europe. In the case of a deceased donor from Europe, NHSBT receives the initial notification from Eurotransplant and faxes the information to all the relevant hospitals. Once GOSH accepts the offer, the retrieval team at GOSH prepares the retrieval kit. This includes all instruments, drapes, ice boxes containing melting water ice and perfusion fluids (cardioplegic solution, as well as other suitable fluids in the case of lung retrievals). GOSH staff make arrangements to travel to the location, retrieve the organs and transport them back to GOSH.

Recipient coordinators document all telephone conversations when the hospital receives offers of organs from NHSBT. The log sheet includes records of timings, matters discussed and what the decision was. A hard copy of donor and organ characterisation information is obtained using the Electronic Offering System (EOS) which is filed in the patient notes. The receipt time, out of ice time, reperfusion time and total ischaemic time for organs are recorded in the recipient's notes on a newly developed log sheet. Surgical notes are also recorded in the in-house electronic document database.

Abdominal organ pathway:

Surgeons from Guy's Hospital, London, who hold contracts to work at GOSH, implant kidneys from deceased donors and from living donors into paediatric recipients. Living donors are characterised at Guy's Hospital. The Guy's Hospital surgical team retrieve kidneys from living donors in the morning and the donor coordinator, registrar or the transplant surgeon at Guy's Hospital accompany the transported kidney to GOSH. Implantation into paediatric recipients at GOSH takes place in the afternoon. The establishment is licensed to work with pancreata, however, no activity has taken place using the pancreas to date.

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 assessment criterion is not applicable. A SN-OD is based at the hospital under NHSBT's licence and undertakes this activity in relation to paediatric donors.	**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 fully met. The majority of characterisation is undertaken by NHSBT for deceased donors or at Guy's Hospital where living kidney donors are characterised. Additional tests that may be required following receipt of an organ will be conducted under the licence held by GOSH. Such tests are rare but may include histopathology to investigate the present of potential malignant neoplasia. Living donation does not take place 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. Additional characterisation and testing on organs from the deceased in order to collect non-mandatory information detailed in Part B of the Annex to the Directive may be undertaken. These tests may include verification of blood grouping and cross matching.	**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's Records Retention and Disposal Schedule (issued in March 2013) states that health records are kept in accordance with the NHS code of practice retention schedule, which, in the case of transplantation, is 30 years.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The GOSH Laboratory Medicine Service is accredited by clinical pathology accreditation (CPA) and provides histopathology services for non-routine organ characterisation requested by the surgeon. The establishment also uses the Clinical Transplantation Laboratories at the Royal London Hospital and Guy's Hospital for blood and tissue type (cross matching) confirmatory testing. These are also accredited by the CPA.	**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. A copy of the HTA Form A arrives with the organ. Information held on EOS can also be downloaded to a local printer and is stored in the donor file. Both teams at the establishment have adopted National Operating Procedure (NOP) 006, Transfer and storage of donor and organ characterisation information and storage of traceability data. <u>Cardiothoracic team:</u> GOSH employs recipient co-ordinators who receive the initial offer of organs. All staff in the team access the EOS using computers or mobile phones to obtain information on deceased donor and organ characterisation. Further information as required is obtained from telephone conversations with a SN-OD. The recipient co-ordinator liaises with the relevant clinicians and surgeons before the organs are accepted for transplantation. The recipient co-ordinator records conversations in a log sheet which includes a check list. EOS data is printed and provided to the surgical team. <u>Renal team:</u> The establishment is made aware of a potential donor by a SN-OD who then relays the donor's identification number to the establishment. Characterisation information on the donor and organ is retrieved from EOS. EOS mobile is used at this initial offer phase. The transplant surgeon is the point of contact for initial offers. In the case of living donors, surgeons from Guy's hospital have access to donor and organ characterisation information before they attend GOSH to implant the kidneys as retrieval of kidneys takes place at Guy's hospital.	**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. Within the UK, consent for organ donation from the deceased is covered by NHSBT's HTA licence. The cardiothoracic team undertakes retrievals in Europe. The retrieval surgeons rely on NHSBT to provide assurance that consent is in place. This is because retrieval surgeons may not be fluent in the language or have awareness of local consent requirements. Staff at the hospital do not procure organs from living donors. Organs from living donors are consented for and retrieved at Guy's Hospital, which is licensed by the HTA.	**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 policy states that all devices and related accessories used must be authorised by the biomedical engineering and procurement departments. Only CE marked re-usable or single use medical device/equipment is procured, in accordance with 2007/47EC. Records of material and equipment used in retrieval of organs are retained in the medical notes. Both teams have adopted NOP 004 Management of procurement material and equipment in deceased and living donation and transplantation.	**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. The Trust Decontamination Policy (issued April 2012) covers the sterile services and the medical equipment disinfection unit. GOSH decontamination services Sterile Services Department is accredited under 2007/47EC.	**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. The establishment does not procure organs from living donors.	**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 R2. Both teams have adopted National Operating procedure NOP 004 Management of procurement material and equipment in deceased and living donation and transplantation.	**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 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. Batch numbers are recorded on the HTA A forms in the case of retrievals from Europe and on HTA B forms if perfusion were to take place prior to transplantation. An example of a completed A form was seen from a recent Eurotransplant retrieval.	**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. GOSH arranges transport when its staff retrieve organs from deceased donors in Europe. The hospital uses the same transport provider as NHSBT and only accepts offers of organs if the transport time is less than four hours. In the case of organs from living donors which are retrieved at Guy's Hospital, the surgeons or donor co-ordinators based at the hospital transport the organs to GOSH. Both teams have adopted NOP 003 Labelling and transport of organs in deceased and living donation and transplantation. Both teams have also implemented their own documents to improve traceability of the organ pathway, including, such as the cardiothoracic organ receipt form and the renal transplant transfer form.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment currently uses kidney transport boxes supplied by NHSBT which the HTA regards as being suitable. Other cool boxes are used to transport liver, heart and lungs. However, the establishment intends to use NHSBT approved transport boxes for all organs when these become available.	**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. In the case of deceased donors, where organs are retrieved in the UK, NHSBT is responsible for labelling and provides the contact details for the duty office at NHSBT instead of the address of the hospital where retrieval took place. Both teams have adopted NOP 003 Labelling and transport of organs in deceased and living donation and transplantation.	**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. Organs may be retrieved from Europe several times each year. These are accompanied by the completed HTA A form. NHSBT uses EOS to provide reports on organ and donor characterisation relating to organs from deceased donors.	**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. Transport arrangements are made by NHSBT for deceased organs. The renal team works closely with another HTA licensed establishment which retrieves organs from living donors and, which manages transport arrangements under its licence.	**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 implanting surgeon is provided with the required information and final checks are undertaken of the suitability of the organ before it is implanted into the recipient. The cardiothoracic team have a surgical safety checklist and a retrieval team checklist to ensure information is verified during retrievals in Europe. Both teams have adopted NOP 002 Verification of donor identity, consent/ authorisation and organ and donor characterisation in deceased and living donation and transplantation.	**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. Conditions relating to preservation and transport of the organ are verified when the organ is received in theatre.	**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. The implanting surgeons document decisions relating to risk / benefit in the patient 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. Both teams have adopted NOP 006 Transfer and storage of donor and organ characterisation information and storage of traceability data.	**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. Unique identification (ID) numbers for deceased donors in the UK are generated by NHSBT. Unique donor ID numbers are also generated for donors in Europe when Eurotransplant communicates with NHSBT.	**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 cardiothoracic and abdominal transplantation team follow different procedures – The date and time of receipt of cardiothoracic organs is recorded on the log sheet, which is filed in the patient notes. In the case of kidneys and organs retrieved from Europe, staff record the time of receipt in the theatres. All records are kept 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. The establishment reports incidents within the Trust and to NHSBT. Both teams have adopted SOP3888 Reporting an organ donation or transplantation incident to NHSBT, which covers on-line reporting to NHSBT. The renal team has further adapted this as SOP3888/2, in line with recent updates from 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.	Refer to 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. Staff confirmed third parties, such as those engaged in testing would report serious adverse events and reactions to the establishment within 24 hours of discovery. The audit team reviewed a copy of the agreement with the establishment's testing laboratory. This confirmed that testing would be provided by a CPA or European Federation for Immunogenetics accredited laboratory and that the laboratory would adhere with all clinical governance requirements.	**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 Trust has policies which ensure that all staff are competent and suitably qualified to perform their activities.	**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. The Trust's Learning Education and Development Section ensures that all statutory and mandatory training and on-going training needs are met. Staff have regular appraisals and their competencies are assessed.	**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. Activities such the review of donor and organ characterisation, perfusion of organs and packing of organs for transport, in addition to retrieval and implantation of organs are performed under the guidance of a medical practitioner. Both teams have adopted NOP 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.	P3	Neither team is likely to reperfuse an organ before transplant, for clinical reasons. This means that the field for the perfusion fluid batch number on the HTA B form is often left blank. To more clearly indicate that reperfusion has not taken place, the establishment is advised to consider a more positive act, such as striking the field through.
2.	S1	The renal team has updated its SOP for reporting serious adverse events and reactions in line with the more recent NHSBT version, SOP3888/2. The cardiothoracic team is advised to do the same.
3.	S3	The establishment has a written agreement in place with its testing laboratories. Staff confirmed there is a good relationship with the third party undertaking tests and they would receive serious adverse event and reaction reports. The written agreement supports this implicitly, through the need to use CPA laboratories and the need for the third party to adhere to all clinical governance requirements. The establishment is advised to address this criterion more explicitly in the contract. The contract is shortly due for review. At that point the establishment may wish to consider including wording which specifically requires the third party to: report any serious adverse events and reactions to the licence holder within 24 hours of discovery.
4.	N/A	Both teams have adopted the NOPs as well as putting in place new, supporting documents to improve the traceability, quality and safety of the organ along its pathway. The renal team has substantially adapted the NOPs to suit its practices. The cardiothoracic team is advised to review its NOPs to ensure they suit its practices and reflect the new documents in place to support the team's work.

Concluding comments

There is good communication between clinical staff, transplant surgeons and transplant coordinators, both within the individual transplant teams and with donor adult hospitals. For example, GOSH employs an adult transplant surgeon, to further contribute to high quality care at the establishment. The donation team and retrieval/implantation teams are “walled apart” to ensure that there is no conflict of interest. The establishment maintains strong links with testing laboratories and staff said they have good access to samples and results. Since the first audit the establishment has worked to improve its documentation and ensure better consistency in its processes.

The HTA has given advice to the establishment with respect to record-keeping, serious adverse event and reaction reporting and ongoing review of its policies and agreements.

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

Report sent for factual accuracy: 19 December 2013

Report returned with comments: 20 January 2014

Final report issued: 22 January 2014

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 preventive 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 preventive actions within 3-4 months of the issue of the final audit report.

Follow up actions

A template corrective and preventive 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 preventive 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.