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 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.

19-20 October 2016

Summary of Audit findings

Great Ormond Street Hospital (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	**Heart, lung, kidney, liver and pancreas**	**R, P, T**
Paediatric - deceased	**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

Recipient	Organ type	Activity
Paediatric	**Heart, lung, 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

Great Ormond Street Hospital (GOSH) has been licensed by the HTA since August 2012. The hospital provides treatment for children up to 18 years old. Transplants are undertaken by two independent teams - the cardiothoracic team and the abdominal team – responsible for transplanting hearts, lungs and kidneys respectively.

Whilst the hospital is licensed for procurement activities, staff based at the hospital do not currently undertake retrieval of organs from paediatric donors. When specialist knowledge and skills are required, staff may attend organ retrievals at other hospitals and provide advice to National Organ Retrieval Service (NORS) teams. The establishment will retain the licence for procurement activities and will inform the HTA should these activities re-commence.

This was the second audit of the establishment and included a visit to key areas where transplants are undertaken and discussions with key members of staff who work under the licence.

Cardiothoracic organ pathway:

Recipient co-ordinators and Clinicians discuss options for transplantation with parents of potential recipients and with the recipients themselves where they are competent and have capacity to consent. The parents and potential recipients are informed that since no donor is perfect, they may be offered organs from donors who smoke, have malignancies or other conditions which may impact on the quality of the donated organs. These discussions take place as recipients are listed for transplant and form part of the consent process so that should such organs be offered, recipients and their families have had an opportunity to consider this type of transplant. In addition, recipients and/or their families are asked to consider if they will accept lungs from a donor who is larger than the recipient and which therefore may need to be trimmed prior to transplant. Trimming of lungs helps to increase the pool of potential donors who would otherwise be excluded for consideration due to the size mismatch between the donor and recipient. Discussions regarding the above and the decision to consent or not to consent to receiving this type of transplant are recorded and available to staff who receive donor organ offers. Once on the transplant list, the immune status of potential recipients is tested and continues to be monitored every three months so that the most recent results can be used for virtual cross matching when an organ from a donor is offered for transplantation.

Recipient co-ordinators receive offers of organs from the Duty Office at NHSBT. The co-ordinator contacts the on-call Transplant Consultant and Surgical Consultant to discuss the offer and information provided by NHSBT via the electronic offering system (EOS). The co-ordinator documents phone calls and actions as well as timings on a log sheet which is referred to as ‘the transplant co-ordinator log sheet’. The Surgical Consultant always speaks directly to the Retrieval Surgeon and will only accept the organ once the Retrieval Surgeon has seen the organ and is satisfied that it is suitable for transplantation. Donor and organ characteristics relating to organs offered by Eurotransplant are first provided to NHSBT who in turn send the details to the recipient co-ordinator at GOSH for consideration.

The recipient co-ordinator arranges for the potential recipient to be admitted into GOSH if the organ transplant is likely to go ahead. Virtual cross matching of the donor and potential recipient takes place at an immunological testing facility. Once the organ has been accepted, NHSBT arranges to transport the organ to GOSH. Organs are received by staff at Theatre Reception and taken to the anaesthetic room, where it remains, until just prior to implantation. Three separate briefings take place in theatres; the initial brief where members of the team are introduced, time out brief which takes place just before implantation and a final brief following transplantation.

The recipient co-ordinator takes the donor blood sample which is packaged along with the donor organ, to the Microbiology/Virology Laboratory at GOSH which has CPA accreditation, with a request to repeat donor virology testing. NHSBT will already have undertaken donor testing as part of donor characterisation when the organ was offered to establishments. It was unclear to the HTA audit team if the laboratory staff were aware that these tests related to the donor as the samples were logged onto the laboratory information management system under the recipient's records, although annotated as a donor sample. In addition, the laboratory may not have been informed if the blood samples were post mortem samples or if they had been taken before the donor's death. During the audit the HTA team were informed that the cardiothoracic team intended to review the practice of repeating donor testing.

The team uses several forms to record key steps in the process. The organ receipt form documents the checks completed when the box containing the organ is received at GOSH. The pre-transplant checklist documents the ODT number of the donor issued by NHSBT, checks carried out on the level of ice within the box and the integrity and condition of the organ prior to implantation. Key timings such as receipt time, out of ice time, perfusion fluids used and total ischemic time for the organ are also recorded. These documents are attached to the co-ordinator log sheet together with a paper copy of the EOS donor and organ characterisation information and completed HTA B form and are filed in a 'Transplant file' which is stored away from the recipient's clinical notes. Once an organ has been implanted, the donor's spleen and lymph nodes are sent to the laboratory for cross matching.

Training for recipient co-ordinators is documented in the Staff Skills, Competencies and Experience record.

Abdominal organ pathway:

Surgeons from Guy's Hospital London, who work under a contract with GOSH, implant kidneys from living and deceased donors into paediatric recipients. Living donors, who in many cases belong to the same family as the recipient, are assessed and worked up at Guy's Hospital where organ retrieval takes place under the authority of the HTA licence granted to Guy's Hospital. GOSH arranges for the kidney to be transported from Guy's Hospital to GOSH where implantation takes place. Renal surgeons work closely with renal physicians based at GOSH.

The Duty Office at NHSBT offers organs from deceased donors and is also involved in co-ordinating transport and information when organs from paired or pooled living kidney donors are implanted into recipients. The offer of an organ from a deceased donor is received by the transplant surgeon at Guy's Hospital, who communicates with the renal physician at GOSH before the kidney is accepted. The surgeon continues to check the donor and organ characterisation information on EOS until just before the organ is transplanted into the recipient to ensure that they are aware of any updates.

Details of kidneys received at the theatres, including the donor ODT number and packaging conditions are recorded on the Tissue register which is kept in Theatre 2, which is the designated renal list/transplant theatre. The register includes a reminder to staff to check and top up the level of ice in the box if required. A transplant checklist, based on the World Health Organisation (WHO) surgical safety checklist, is used to record checks carried out during the preoperative stage (team brief), checks on patient, organs (time out) just before surgery and post operation checks (sign out). Organ details including retrieval damage, perfusion fluids used in theatres at GOSH, cold and warm ischaemic times are recorded in the Operation Record which has a note reminding staff to ensure that the transplant checklist has been completed. A sample of the transport fluid in which the kidneys were packed is sent to the Microbiology/Virology laboratory for testing to detect microbial contamination. The HTA

team were informed that around 5% of samples were contaminated and recipients was given appropriate prophylactic treatment.

Document review:

Several sets of recipient clinical notes and associated records was reviewed during the audit. The included records relating to a heart allocated by Eurotransplant, and retrieved by the NORS team based at another HTA licensed establishment, a lung transplant from a deceased donor and two kidney transplants from living donors. Records reviewed included as appropriate, printouts from EOS, consent forms, Eurotransplant donor and organ report, transplant co-ordinator logs, HTA B forms which had details of perfusion fluids used, operation records and checklists. A heart recipient's consent form for donation of heart valves from their explanted heart was also reviewed.

Staff are aware of the procedure for reporting incidents to NHSBT; these incidents are also reported and investigated within the Trust. The HTA audit team reviewed an incident relating to procurement and transport of an organ to GOSH which was reported to NHSBT and discussed at the Cardiothoracic Advisory Group set up by NHSBT.

The HTA audit team reviewed several Trust documents. The Contract for Decontamination Services was made with a service provider certified under ISO 13485:2003 and EN ISO 13485:2012 for cleaning, disinfection, packing, moist heat sterilisation and hydrogen peroxide sterilisation of instruments, theatre trays, procedure packs and re-usable medical devices.

The Medical Equipment Policy covers procurement, maintenance, cleaning, decontamination and reporting of incidents relating to all medical equipment (see advice item 1).
The Trust uses a pre-purchase questionnaire when purchasing equipment which includes gathering information on CE marking and compliance with the relevant medical Devices Directive and states that 'medical devices shall have valid CE marking'.

The Service Level agreement between GOSH and the organisation responsible for transporting organs was reviewed. The agreement states that 'incidents where harm to the package in transit have occurred or a 'near miss' will be treated as a priority' and references the SAEARs Standard Operating Procedure (SOP) on reporting incidents to NHSBT.

The Trust's Record Retention and Disposal Policy states that Donor records are kept for 30 years post transplantation and 'Records not otherwise kept or issued to patient records that relate to investigations or storage of specimens relevant to organ transplantation should be kept for 30 years'.

Compliance with HTA assessment criteria

All applicable HTA assessment criteria have been assessed as fully met.

The audit did not assess HTA assessment criteria CT1, R1, R2, R3 and R4 as the establishment does not currently undertake retrieval of organs from paediatric donors. The HTA informed the establishment that it could retain the licence for procurement activities, but must inform the HTA should these activities re-commence.

Advice

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

No.	Assessment Criterion	Advice
1.	P1	The establishment is advised to review the Medical Equipment Policy which was due for review on 3 August 2016. The typographical error in The Medical Devices Regulations referred to in Section 2, SI 1994/3037 should be amended to SI 1994/3017.
2.	P3	The establishment is advised to amend the Operation Record form completed by the implanting renal surgeon to clarify the section relating to perfusion fluids. *Following the audit, the team amended the form to distinguish between perfusion which takes place during retrieval and perfusion which takes place once the kidneys are received at GOSH.*
3.	TP5	The establishment is advised to revise the Service Level agreement for the provision of transport for transplant services in order to reference the updated document SOP3888/2 – Reporting an Organ Donation or Transplantation Incident to NHSBT (updated November 2013).
4.	I2	The establishment is advised to update the Transplant check list used by the renal team during the 'time out' stage to confirm that the implanting renal surgeon has received and verified the most up to date donor and organ characterisation prior to implanting the kidney. This would apply when kidneys from deceased donors are received for transplantation and there is a handover between the surgeon who receives and accepts the offer of a kidney and the surgeon who implants the kidney into the paediatric recipient.
5.	TC3	The Trust's Records Retention Policy states that all records relating to transplants are kept for 30 years. The establishment is advised to ensure that this policy also covers records kept by the Cardiothoracic team (Tranplant Files) and the Abdominal Team (Operation Records and Transplant Register) as these records are not included in the recipient's clinical notes. The establishment can consider updating the Trust's Records Retention Policy or updating National Operating Procedure 006 as appropriate.
6.	NA	The establishment is advised to implement a system to ensure that the recipient co-ordinator is aware of, and uses, the latest version of the log sheet to document communications between NHSBT Duty Office, the transplant consultant and the surgeon. The establishment is also advised to consider sharing information on documentation and forms used by the cardiothoracic team and the abdominal team to support transplants. This would help to ensure sharing of best practice.

Concluding comments

There are robust systems in place to complete the relevant HTA B forms and return the forms

to NHSBT within seven days, thus ensuring traceability. The Cardiothoracic team has good systems in place for record keeping. The Transplant co-ordinator log details communication between the Duty Office at NHSBT, transplant surgeon, transplant consultants, laboratories, theatre staff and the ward and records the time of these interactions.

The abdominal team file all transplant related paperwork in individual folders on a dedicated shelf near the theatres where kidney transplants take place. Blank forms relating to pre-transplant and post-transplant stages are kept in each folder so that they can be easily accessed by visiting surgeons from Guy's Hospital, completed and filed.

Perfusion fluids are stored in two fridges; one near the cardiothoracic theatres and the other near the renal theatre. Pharmacy monitors the temperature of these fridges to ensure that the fluids are being stored in accordance with the manufacturer's recommendations. Pharmacy also check the stock levels and expiry date of perfusion fluid in the fridge near the cardiothoracic theatres to ensure that the stock is sufficient, and within the expiry date. Renal theatre staff are responsible for stock checks and checking the expiry dates of perfusion fluids stored in the fridge near the renal theatre.

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

Report sent for factual accuracy: 16 November 2016

Report returned with comments: 30 November 2016

Final report issued: 1 December 2016

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

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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.
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.
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.
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.