Site visit audit report on compliance with HTA requirements

Bupa Cromwell Hospital

HTA licensing number 40011

Licensed for

- **Procurement Activities: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), retrieval of an organ (R)**

- **Transplantation Activities: organ characterisation (OC), preservation of an organ (P), implantation of an organ (I)**

Under the Human Tissue Quality and Safety of Human Organs Intended for Transplantation Regulations 2012

26 February 2013

Summary of Audit findings

The HTA found that Bupa Cromwell Hospital (the establishment) had met the majority of the HTA assessment criteria.

The establishment was found to have met the majority of assessment criteria, but some shortfalls were found, mostly in relation to documentation of standard operating procedures governing the licensed activities. The establishment intend to produce a written operating procedure using information detailed in the National Operating Procedures that is relevant to their activities.

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, 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, 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 inspection activities undertaken

The Bupa Cromwell Hospital is situated in central London and provides private healthcare. The establishment runs a living kidney transplant programme and both procurement (nephrectomy) and transplant activities take place on the same site. Until recently the establishment also offered a living liver transplant programme, and intend to recommence when suitable staff are in post to provide this service.

Living kidney donor and recipient pairs referred to the Bupa Cromwell Hospital are most often related and the establishment accepts directed donations only. The majority of patients are from overseas but will be resident in the UK for the duration of donor and organ characterisation, transplantation and post-transplant care. The establishment provides a 24 hour on-site translator service for patients who do not speak English.

All donors and recipients are adults and the establishment does not offer a paediatric transplant service.

Living kidney donors are characterised at the establishment under the care of the consultant nephrologist and renal transplant surgeon. Tests required for donor / organ characterisation are carried out by third party, CPA accredited laboratories. One of the laboratories used is situated on the hospital site.

The transplantation unit is staffed by a small, close knit team and pre and post transplant care is currently consultant led. The establishment are in the process of moving towards more of a nurse-led service for patient care and as such have initiated and implemented a training programme.

Living donor nephrectomies are carried out by the transplant surgeon who will also be responsible for perfusing and preserving the kidney and will perform the organ implantation into the recipient. The organ remains in the operating theatre at all times and donor nephrectomy and recipient implantation are performed in the same operating theatre.

The unit carried out 11 living kidney transplants in 2012 and expect a similar number in 2013.

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 does not receive any deceased donor organs for transplant.	**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. All mandatory, and where required, additional donor tests are carried out as part of living donor work up. Overseas patients will often have had donor and organ characterisation tests carried out in their own countries prior to arrival in the UK. In order to ensure the safety of the donor and recipient, all mandatory and complementary tests will be repeated by the establishment in the UK. The establishment have a documented checklist, 'donor work up' that provides a record of all checks that have been carried out. Donor and organ characterisation information is also recorded in surgical assessment forms, care plans and evaluation forms. The HTA has provided advice relating to this criterion.	**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. Reference is made to CT2 above.	**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 establishment have a documented procedure, Bupa Cromwell Hospital Records Management Policy' that details all information relating to donor and organ characterisation is retained for 30 years. Donor and recipient medical notes have a sticker on the front identifying that they are an organ donor or organ recipient which allows them to be clearly identified as requiring this retention period.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Donor and organ characterisation tests are carried out in two laboratories provided by the same third party. The establishment has a service supply agreement in place with the third party. The establishment confirmed that both laboratories are CPA accredited and this has been subsequently confirmed on the CPA 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. Organ procurement and implantation are both carried out at the establishment. The consultant nephrologist is responsible for requesting the majority of the tests required and will discuss the results of the tests with the consultant surgeon during the donor work up. The same surgeon is responsible for planning and carrying out the retrieval and implantation operations and has full access to all relevant information in advance of the transplant procedure. The establishment has a written protocol that covers this assessment criterion that was produced by the consultant nephrologist and transplant surgeon, entitled 'protocol for living related renal transplantation'. The audit team acknowledge that the transfer of information relating to donor and organ characterisation is much less time-dependent in living donation. The HTA have provided advice in relation to this written procedure.	**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. The surgeon who carries out the procurement will also be responsible for obtaining consent from the living donor.	**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 establishment have a written procedure entitled 'Procedure to ensure correct processes are followed when buying medical devices and equipment'. This procedure details that all material and equipment procured by the establishment meet the requirements of the Medical Devices Regulations 2002. Materials and medical equipment being used in accordance with the Medical Devices Regulations 2002 was covered by the following: 'Clinical engineering department policy and procedure (CED-001)'.	**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 establishment have a third party who is responsible for the cleaning and sterilisation of reusable instruments. A service level agreement was in place and evidence provided to the audit team. In addition the team also saw an EC certificate from the provider as evidence on validation and quality assurance of sterile services.	**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.	There is a minor shortfall against this assessment criterion. The vast majority of living donors are overseas patients who will be under the care of the establishment until discharge, usually a minimum of two weeks post donation. When discharged, a report will be sent to the donors general practitioner (or equivalent) detailing the donors medical status and any follow-up checks that need to be routinely carried out. Patients are informed that they may return to / contact the establishment if necessary for care or advice. The discharge report does not contain any information relating to identifying and reporting any events that may arise and have the potential to affect the recipient – such as the development of malignancy in the donor that was unknown at the time of donation.	**Minor**

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. Reference is made to 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. Reference is made to R2.	**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. Copies of recently completed HTA A and B forms were provided during the audit, confirming that batch numbers of perfusion fluids used are recorded as required.	**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 not applicable – the establishment do not transport any organs.	**N/A**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is not applicable – the establishment do not transport any organs.	**N/A**
TP3) The organ shipping container used for transporting organs from the licensed premises is labeled with the information specified in paragraph 8(b) (i) to (iv) of the SI, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is not applicable – the establishment do not transport any organs.	**N/A**
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 not applicable – the establishment do not transport any organs.	**N/A**
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 not applicable – the establishment do not transport any organs.	**N/A**

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 surgeon responsible for implanting the kidney into the recipient will be the same surgeon who will have carried out the nephrectomy in the living donor. The surgeon will have had full access to all relevant information in advance of the transplant procedure and will have been involved in the living donor work up process. The establishment has a written protocol that covers this assessment criterion; 'protocol for living related renal transplantation'. The establishment uses the WHO surgical checklist and will verify the donor identity and all relevant information in advance of anaesthetising the recipient. The HTA have provided advice in relation to this assessment criterion.	**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 not applicable. The establishment does not receive any organs that have been transported.	**N/A**
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 establishment do not accept living donors who are high risk and will have enough time to gather all relevant information required to characterise the donor and organ. A risk benefit analysis would be documented in the surgical assessment if required.	**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.	There is a minor shortfall against this criterion. The establishment have recently introduced the use of HTA A and B forms and provided copies of forms during the audit. There were some minor discrepancies and omissions of information from the forms observed by the audit team. As such the audit team suggested that the establishment should include a check HTA A and B forms for completeness of information as part of the procedure. The audit team were provided with verbal assurance that the forms were returned to NHSBT within 7 days. There is currently no written procedure that documents who fills in the forms, and who is responsible for checking and returning the forms to NHSBT. The shortfall against this assessment criterion relates to the requirement for a written procedure.	**Minor**
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. All donors and recipients are given a seven digit Cromwell Hospital Number that is also used on all samples used for laboratory tests. Samples are also given a unique bar code for tracking.	**None**
TC3) A record (date and time) of the transportation of organs arriving at/or leaving the establishment is kept for 30 years as part of the traceability information.	This assessment criterion is not applicable – the establishment do not receive transported organs.	**N/A**

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.	There is a minor shortfall against this assessment criterion. The establishment has a clinical incidents and risk management strategy document that details responsibilities and procedures for risk management. The establishment also has a developed system for electronic submission and tracking of reported incidents. However, the establishment did not have operating procedures in place to identify and manage serious adverse events and reactions, which constitutes a minor shortfall.	**Minor**
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.	Reference is made to S1, above. The consultant transplant surgeon was aware of the requirement to report any adverse incidents to NHSBT and had previously done so in relation to NHS work under another transplant centres licence. However, not all staff were aware of what constituted a serious adverse event and reaction and the timeframe for reporting or how to report. The establishment advised that they intend to adopt the SOP 3888/1 (Reporting an organ donation and transplantation incident to NHSBT) produced by NHSBT and detailing how and when to report via the online portal. The establishment also advised that they plan to include training on identifying and reporting serious adverse events and reactions as part of their rolling staff training programme.	
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.	There is a shortfall against this assessment criterion. The establishment have a service supply agreement in place with the with the third party laboratory provider who carries out tests for donor and organ characterisation on their behalf. This agreement does not include any reference to identifying serious adverse events or instruct the laboratories how and when to report any such occurrence to the licence holder.	**Minor**

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. Examples of training and qualification documents were exhibited during the audit. The competence of surgical staff is assessed by the appraisal process. The audit team were provided with the most recent appraisal document from the consultant surgeon as evidence of competency. Nursing staff involved in donation and transplantation provided their personal professional development portfolios as evidence of training and competency.	**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 establishment have recently initiated a rolling training programme for staff involved in donor and recipient patient care. The establishment have also have an internal action to support staff to attend training days and identify further training opportunities. The HTA have given advice against this criterion.	**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. All patients (living donors and recipients) are directly managed by an anaesthetist, surgeon or physician involved in the transplant. This covers all activities that are required to be performed under the advice and guidance of a registered medical practitioner. The establishment have a documented procedure, Protocol for living and related renal transplantation' which covers activities carried out and responsibilities of personnel. The HTA have provided some advice in relation to this assessment criterion.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	The HTA advises the establishment to ensure that information relating to donor history and social behaviour that form the mandatory donor data set detailed in Annex A of the Framework Document (The Quality and Safety of Organs Intended for Transplantation – a documentary framework) specifically, past or present history of IV drug abuse and also recent foreign travel to any areas of endemic disease is always documented even where the answer is no.
2.	CT6	The HTA advises the establishment to review the National Operating Procedure NOP 006 – Transfer and storage of donor and organ characterisation information and storage of traceability data, and include procedural details relevant to the activities carried out by the establishment into either a new written operating procedure or their existing SOP.
3.	I1	The HTA advises the establishment to review the National Operating Procedure NOP 002 – Verification of donor identity, consent / authorisation and organ and donor characterisation in deceased and living donation and transplantation and incorporate procedural details relevant to the activities carried out by the establishment into a new document or their existing SOP.
4.	GN2	The HTA advises the establishment to provide staff with training in relation to any newly implemented written operating procedures and identification of serious adverse events and reactions. Serious adverse event and reaction reporting for organs intended for transplantation – guidance for licence holders has been provided to the establishment for this purpose.
5.	GN3	The HTA advises the establishment to review the National Operating Procedure NOP 002 – Verification of donor identity, consent / authorisation and organ and donor characterisation in deceased and living donation and transplantation and incorporate procedural details relevant to the activities carried out by the establishment into a new document or their existing SOP.

Concluding comments

The HTA audit team would like to acknowledge the staff at Bupa Cromwell Hospital and thank them for their engagement in the lead up to and during the HTA audit process. All staff involved in the audit were open and constructive during discussions and provided the audit team with a comprehensive overview of the living donor programme and activities carried out under Bupa Cromwell's HTA licence.

The audit team saw a number of examples of good practice. The Bupa Cromwell hospital offers good facilities for patient care, providing a 24 hour interpreter service and a live-in resident medical officer (RMO). There are also low patient to staff ratios.

The hospital have a system in place to alert medical staff to patients with the same or similar

name, as many living donors and recipients are related and will have the same surname. The patients are highlighted on the patient white board using a yellow sticker and allocated rooms geographically separated to reduce the risk of a mix up.

The audit team considered the staff at Bupa Cromwell Hospital had a positive approach to the audit process and also new legislative requirements that relate to organ donation and transplantation. This was evidenced by the fact that staff had carried out a gap analysis and produced an action plan in advance of the audit. A rolling training programme had also been recently introduced for staff involved in organ donation and transplantation. The audit team also noted as good practice that staff had identified the potential requirement for a contingency arrangement for transportation of organs in the very unlikely event that a living donor kidney would not be suitable for transplant into the intended recipient and was offered for National allocation.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent for factual accuracy: 18 March 2013

Report returned with comments: 21 March 2013

Final report issued: 3 April 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: 04 December 2013

Appendix: Classification of the level of shortfall (HA)

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 recipient patient or to a living donor,
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 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 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 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 inspection.
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 inspection 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 inspection 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.