Site visit audit report on compliance with HTA requirements

Imperial College Healthcare NHS Trust

HTA licensing number 40044

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), 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

6 March 2013

Summary of Audit findings

The HTA found that Imperial College Healthcare NHS Trust (the establishment) had met the majority of the HTA assessment criteria.

The establishment was found to have met the majority of assessment criteria. One shortfall was found, in relation to instructing third parties to identify and report serious adverse events. The establishment also have an outstanding action in relation to the reporting of serious adverse events and reactions within the applicable timeframes.

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 donor)	**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 (living and deceased) Pancreas (deceased only)
Adult Recipients	**OC, P, I**

Transplantation Activities: organ characterisation (OC), preservation of an organ (P), making arrangements to transplant an organ (T), implantation of an organ (I)

Background to the establishment and description of inspection activities undertaken

The Imperial College Renal and Transplant Centre at Imperial College Healthcare NHS Trust is situated at Hammersmith Hospital and provides adult kidney and pancreas transplantation services.

The establishment runs a living kidney transplant programme and both procurement (nephrectomy) and transplant activities take place on the same site. The establishment also receive deceased donor organs for simultaneous kidney / pancreas (SPK), pancreas after kidney (PAK) and kidney only transplantation.

All living 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 living donor coordinator, consultant nephrologist and renal transplant surgeon. Tests required for donor / organ characterisation are carried out by the Imperial College Healthcare Trust's laboratories, all of which are CPA accredited.

Deceased donor organs are received at the transplant high dependency unit and the team have a well established, procedure for organ receipt that includes documented checks on the integrity of the packaging and levels of melting water ice.

Living donor nephrectomies are carried out by the transplant surgeon who will also 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 carries out approximately 150-200 kidney transplants per year of which 50 – 60 % are live donor transplants. The centre also offers a blood group (ABO) incompatible programme.

The establishment have adopted all the relevant National Operating Procedures and the standard operating procedure (3888/1) detailing how to report serious adverse events and reactions via the NHSBT portal. The decision that the renal transplant centre will follow the procedures as clinical guidelines has been ratified at the meeting of the Renal Board and the relevant NOPs have been published on the Trust's intranet. The HTA have provided advice in relation to the use of these documented procedures in the advice section of this report.

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.	Deceased donor organs are received at the establishment for transplant, but information for this assessment criterion is obtained and transmitted under NHS Blood and Transplant's (NHSBT) licence.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. This criterion is applicable for living donors and organs and any subsequent tests conducted under this licence for deceased donor organs. All mandatory and complementary donor tests are carried out as part of living donor work up. The establishment have a documented checklist, 'donor work up' that provides a record of all checks and tests that have been completed to assess the suitability of the living donor in order to make a decision to proceed to donation. Donor and organ characterisation information is also recorded in the donor's medical notes. 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 provided email communication from the Health Records providing assurance that health records are not destroyed and the current policy is to retain indefinitely. The email also stated that the NHS National Guidelines for Record Keeping is the baseline document used at Imperial College Healthcare NHS Trust.	**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 by the Trust's laboratories. The establishment confirmed that all laboratories used are CPA accredited and provided certificates as evidence of this.	**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 Living Donor Coordinator is responsible for requesting the majority of the tests required and will discuss the results of the test results at the living multidisciplinary team (MDT) meeting. 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 have adopted the NOP 002 – Verification of donor identity, consent / authorisation and organ and donor characterisation in deceased and living donation and transplantation. For deceased organ donation, the renal registrar receives the initial organ offer from NHSBT and will access the donor and organ characterisation information via the electronic offering system (EOS). The registrar will record the information in writing and then discuss with the on call consultant physician who will then discuss with the transplant surgeon in order to make a decision to accept the organ. The HTA have provided advice in relation to the adoption of written procedure NOP 002.	**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 living donor nephrectomy will check consent prior to procurement. The establishment uses the World Health Organisation (WHO) Surgical checklist to confirm consent prior to administering anaesthesia. The establishment does not supply any surgeons to the national organ retrieval service (NORS) teams and does not carry out any local retrieval from deceased donors.	**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 'Medical devices management policy'. This policy ensures the purchase of only medical devices compliant with the technical and legal requirements of the Medical Devices Directives. This policy also required users of medical equipment to sign to say that they have been trained in the Trusts requirements.	**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. All sterilisation of reusable medical equipment is out-sourced and carried out by IH Sterile Services Limited (IHSS). The Trust has a contract in place to govern this process. The contract stated that IHSS are registered with the Medical Healthcare Regulatory Authority (MHRA) and processing operations are undertaken in accordance with MHRA's requirements.	**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. Living donors are extensively followed up. The central point of contact will be the high dependency ward that has been responsible for their post-operative care. All living donors will be given the ward's contact number and encouraged to contact if they have any concerns. Follow up will be frequent in the first twelve months and in accordance with the national guidelines. If a donor dies the centre will actively follow up to determine cause of death and whether there are any implications for the recipient. Follow up reports are submitted to NHSBT between 1 and 10 years post donation. Overseas donors are discharged with a letter highlighting the need to contact if there are any medical concerns. This letter also contains the contact number of the high dependency ward. The establishment described an example of a donor who had developed malignancy and was followed up and discussed at the MDT meeting in order to consider any potential implications for the recipient.	**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. 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. The establishment photocopies the top copy of the HTA A and B forms in order to keep a legible copy on site. Evidence was provided that the establishment record the batch numbers of perfusion fluids and have been routinely doing this since September 2012.	**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. For living kidney implantation the surgeon will have had full access to all relevant information in advance of the transplant procedure. The establishment uses the WHO surgical checklist and will verify the donor identity and all relevant information in advance of anaesthetising the recipient. For implantation of kidneys from deceased donors the registrar will document details to be confirmed by the surgeon. The surgical team will check these details prior to implantation and raise any queries or anomalies. The establishment have adopted the national operating procedure NOP 002: Verification of donor ID, consent and donor characterisation. The HTA have provided advice in relation to adoption of this documented procedure.	**None**
I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ.	This criterion is fully met. The establishment have a documented receipt process and use the form 'Receipt of organ checklist' to verify the conditions of preservation and transport. The establishment have had this process in place since the transplant programme was relocated at Hammersmith Hospital in 2006. The establishment also includes a requirement, as part of the 'Care of the Transplant Patient' training module that competency is assessed to 'demonstrate an in depth knowledge and understanding of receiving an organ onto the ward, the checks that need to be made and the paperwork to be completed'.	**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 audit team were advised that a risk benefit analysis would be documented in the patients' medical notes when conducted.	**None**

Assessment Criteria	Audit findings	Level of shortfall
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment return the top copy of the form to NHSBT within five days via secure fax and send the remainder of the form to NHSBT within two weeks. The establishment have adopted the NOP 006 - Transfer and storage of donor and organ characterisation information and traceability data. Advice is provided in relation to the use of this procedure and ensuring it is reflective of the procedure in practice.	**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. All donors and recipients are identified using their NHS number and	**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 fully met. The establishment record the date and time of all organs arriving and leaving the hospital. Reference is made to I2, above.	**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 assessment criterion is fully met The establishment has a well developed reporting procedure for Trust incidents and have adopted the SOP 3888/1 – Reporting an organ donation or transplantation incident to NHSBT produced by NHSBT and detailing how and when to report via the online portal. The HTA have provided advice against this assessment criterion.	**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.	The establishment have an existing action against this assessment criterion issued with their continuous licence, due to be completed in April 2013. The establishment's staff were aware of the requirement to report any adverse incidents via the NHSBT portal and have now adopted the SOP 3888/1 (see S1 above). The establishment have also identified the need to raise staff awareness in relation to identifying and managing serious adverse events and reactions (SAEARs). The 'live donor MDT' meeting and 'transplant research and clinical practice group' meeting now have a standing agenda item to discuss SAEARs on a monthly basis. During the site visit audit the HTA team identified a serious adverse reaction that had occurred during the fixed term licensing period that had not been reported. The establishment have agreed to report the SAR via the NHSBT portal, at HTA's request.	**Existing action under Assessment Criteria Action Plan – due April 2013**
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 minor shortfall against this assessment criterion. The establishment use the Trust's laboratories to carry out any required donor and organ characterisation tests. The establishment have not yet instructed the laboratories that carry out donor and organ characterisation tests on their behalf, of the requirement to identify and report any serious adverse events and the time frames within which this must be done. This constitutes a minor shortfall. The HTA have also provided advice in relation to this assessment criterion.	**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 all staff is assessed by the appraisal process. 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. Staff are provided with training required to perform their tasks. Nursing staff involved in transplantation are required to complete the 'Renal Care Practitioner Module – learning outcomes and assessment guidelines'. This is a modular based competency assessment framework. The HTA have provided advice in relation to this assessment 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. The establishment provides a consultant led service for transplantation where all relevant medical activities are performed under the guidance of the consultant surgeon or physician. The Trust have adopted the National Operating Procedure NOP 5 – Activities to be performed under the guidance of a medical practitioner 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, 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 ensure that the procedure reflects local practices. The NOP should be amended to be reflective of these local practices so that it may function as a useful reference for the establishment's staff.
3.	TC1	The HTA advises the establishment to review the National Operating Procedure NOP 006 (Transfer and storage of donor and organ characterisation information and traceability data). As above, this review should ensure that the operating procedure details current practices in relation to the return of HTA A and B forms and any other relevant practices included in the procedure.
4.	S1	The establishment have adopted the SOP 3888/1. This SOP should be amended to include who would be responsible for reporting locally. Staff should also be made aware of the procedures.
5.	GN2, S3	The HTA advises the establishment to provide staff with training in relation to any newly implemented written operating procedures and also the identification of serious adverse events and reactions. The HTA also advises that laboratory staff are included in the training sessions or provided with information to allow them to identify potential serious adverse events that may occur in relation to donor and organ characterisation tests. The establishment may find the following document useful when providing this training 'Serious adverse event and reaction reporting for organs intended for transplantation – guidance for licence holders'.
6.	GN3	The establishment have adopted the NOP 005 (Activities to be performed under the guidance of a medical practitioner). This is a generic operating procedure but should still be reviewed to make sure that it reflects the establishment's practices and amended if required.

Concluding comments

The audit team saw a number of examples of good practice. The establishment had a good system for receipt of organs and procedure for checking and documenting that conditions had been maintained during transport. They also had a process for dealing with receipt of more than one organ at one time where organs were kept spatially separated and different members of staff would be responsible for each organ. Nursing staff responsible for receipt of organs were also trained in this process and signed off as competent to receive and check deceased donor organs.

The establishment also has a thorough and rigorous system of following up living donors and also eliminating any potential consequences for recipients by endeavouring to determine the cause of death in deceased, living donors.

The establishment also has a good system for traceability of organs and held records and log books detailing transplant traceability information that dated back to when the transplant service was first transferred to Hammersmith Hospital.

The HTA audit team would like to thank the staff at Imperial College Healthcare NHS Trust for their open and constructive discussions and for provided the audit team with a comprehensive overview of activities carried out under their HTA licence.

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: 3 April 2013

Report returned with comments: 17 April 2013

Final report issued: 24 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: 23 April 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.