Site visit audit report on compliance with HTA requirements

Cardiff and Vale University Local Health Board

HTA licensing number 40037

Licensed for

- **<u>Procurement Activities</u>: donor characterisation (DC), organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), retrieval of an organ (R)**

- **<u>Transplantation Activities</u>: organ characterisation (OC), preservation of an organ (P), making arrangements to transport an organ (T), implantation of an organ (I)**

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

15-16 May 2013

Summary of Audit findings

Cardiff and Vale University Local Health Board (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 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	Liver	Pancreas
Adult living	**DC, OC, P, T, R**		
Adult deceased	**OC, P, T, R**	**OC, P, T, R**	**OC, P, T, R**

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

Licensable activities carried out by the establishment – Transplant activities

Organ type	Kidney	Pancreas
Adult	**OC, P, T, I**	**OC, P, T, I**

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

Cardiff and Vale University Local Health Board (the establishment) carries out both kidney and pancreas transplants in adult patients.

The establishment also provides staff to the abdominal National Organ Retrieval Service (NORS) teams which apart from kidney and pancreas undertake liver retrievals.

Tissue typing and cross matching are performed on behalf of the establishment by a CPA accredited laboratory. Other characterisation tests such as additional histopathological tests and donor serology testing are performed by the establishment's pathology laboratory and hospital testing laboratory respectively.

Transportation of organs is carried out by a specialist courier company on behalf of the establishment under an agreement held by NHSBT.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.	This criterion is not applicable. The establishment is not responsible for obtaining information relating to a deceased donor. This will be carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**N/A**
CT2) Donors and organs are characterised before implantation by the collection of information specified in Part A of the Annex to the Directive.	This criterion is fully met. The establishment has adopted NOP1 which defines donor characterisation as specified in part A of the Annex to the Directive. Donor and organ characterisation information is collected during several pre-assesment visits of a potential living donor as part of the donor work-up. Characterisation information is collected in the 'Live Renal Donor Health History Questionaire'. Other information including virology results is documented in the 'Integrated Care Pathway for Living Kidney Donor' booklet. Advice is given below regarding reflecting the documentation that is used to record characterisation information within NOP1.	**None**
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Part B of the Annex to the Directive.	This criterion is fully met. For deceased donor organs additional characterisation tests will usually be arranged by the SN-OD under NHSBT's licence. These tests are performed at the retrieval centre. If necessary however, extra tests, most commonly histopatological analysis of frozen sections may be taken at the establishment upon receipt of the organ. For living donor cases, if additional tests are required, these will be carried out at the establishment.	**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's newly approved Records Management Policy refers to the Department of Health's Record Management: NHS Code of Practice (2006). The audit team was informed that records relating to transplantation are to be maintained for 30 years.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. During the audit the current CPA acreditation certificate was reviewed for the three laboratories undertaking donor and organ characterisation tests. The tissue typing and histopathology laboratories have current CPA accreditation and certificates were reviewed during the audit. The third laboratory, which undertakes living donor serology testing currently has conditional accreditation by the CPA. Evidence was provided to show that this laboratory was finalising work on the final minor non-compliance and it expected full CPA accreditation in the near future. Advice has been given below regarding this assessment criteria.	**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. Characterisation information for living donors is gathered during donor work-up. The retrieving and implanting surgeons discuss donor and organ characterisation information prior to implantation. For deceased donor organ, the recipient coordinator receives a phone call from NHSBT. The recipient coordinator collects the donor identification number and logs onto the Electronic Offering System (EOS) to collect further data about the donor including information on donor characterisation. Data from EOS is recorded on a Donor Offer form. Donor and organ information is passed verbally to the on call transplant surgeon so they can decide whether or not to accept the organ. If the organ is accepted the recipient coordinator will start to make arrangements for the transplant. If necessary to gather further information the recipient coordinator will liaise with the retrieving surgeon and Specialist Nurse Organ Donation (SNOD). In many cases a virtual cross match between the deceased donor and recipient may be performed. This is made possible by regular monitoring of the immune status of recipients and gathering information on potential sensitizing events when recipients attend the renal clinic or attend prior to transplant surgery. When the implanting surgeon arrives at the operating theatre the recipient coordinator passes the relevant paperwork such as the donor offer form, HTA-A form and any paperwork arriving with the organ to the implanting surgeon for review. The establishment has developed a high level process flow covering the relaying of information to the implanting surgeon. Although the Donor Offer Form contains a call check list to help the recipient coordinator ensure that all of the necessary people have been informed about a transplant there is no way of logging that the key donor and organ characterisation data has been transmitted to the implanting surgeon. Advice has been offered against this assessment criteria below.	**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. Whether procuring organs from a living donor at the establishment or if undertaking National Organ Retrieval Service (NORS) activity, the consent of the donor is checked as part of a surgical safety checklist which is performed before the start of any retrieval.	**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 Medical Equipment Management policy states that purchase and use of medical equipment within the establishment's Trust is prohibited unless the equipment is CE marked. When undertaking NORS activity some medical equipment is additionally supplied by another licensed establishment and is brought to the retrieval site by the scrub nurse in attendance who is based at the other licensed establishment.	**None**
R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. The Trust's Decontamination Service manager confirmed by email that the Trust's Hospital Sterile and Decontamination Unit is appropriately certified and has current ISO 9001:2008 and ISO 13485:2003 certification. Any instruments supplied by another licensed establishment when undertaking NORS activity is returned to the other establishment for sterilisation.	**None**

R4) Endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation.	This criterion is fully met. The establishment organises annual follow up appointments for living donors. Some donors however prefer to be reviewed annually by their local healthcare provider. In these cases the establishment sends a referral letter to the relevant health care provider detailing what assessments should be carried out which include monitoring of blood pressure and kidney function. These referral letters do not include a notice to the donor's clinician or GP to notify the establishment should a donor present with any indications which may have implications for the organ recipient. Advice has been given to the establishment regarding donor follow up letters.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Organ preservation		
P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Refer to R2	**None**
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.	This criterion is fully met. Refer to R3	**None**
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.	This criterion is fully met. During a review of patient notes for both living transplant donors and recipients and recipients of deceased donor organs, evidence was seen that HTA A and B forms contained details of the perfusion fluids and batch numbers used during retrieval and implantation.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Making arrangements to transport an organ		
TP1) The integrity of the organ is maintained during transport and the transport time is suitable to ensure the quality and safety of the organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment uses the NHSBT Kidney Transport Box packing instructions. These contain details of how to secure the transport box and how to pack organs correctly. The establishment have also adopted NOP003 which contains additional details on packing of organs and instructions on how to correctly label the transport box. The establishment may also use a hypothermic perfusion device to transport DCD donor organs which are destined for implant at the establishment. The establishment have developed a flow sheet which contains details on how to pack kidneys into the device ready for transportation. Advice has been given below to the establishment about including the hypothermic perfusion device flow sheet instructions within NOP003.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses NHSBT's kidney transport boxes which have been deemed suitable for transportation of kidneys. The hypothermic perfusion device used for transport of some DCD donor kidneys is CE marked and has been deemed suitable for the transport of kidneys.	**None**
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in paragraph 68 of the framework document, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. NOP003 that has been adopted by the establishment contains details of what information must be included on the labels of the transport box. When using the hypothermic perfusion device, details regarding the labelling of the device is included within the 'National Organ Retrieval Service and Transplant Service Arrangements in Cardiff' document.	**None**

TP4) Transported organs are accompanied by a report on the organ and donor characterisation, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The HTA A form is included as part of the transportation documentation. Additionally, information regarding donor characterisation is uploaded to EOS by the SNOD at the donor establishment. The establishment has adopted NOP003 which details what information must accompany the organ during transportation.	**None**
TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.	This criterion is not applicable. The establishment indicated that they do not hold a contract for the transportation of organs with any transport companies. Deceased donor organs being brought to the establishment have transportation arranged by NHSBT who also hold the contract with the transport company. Where any living donor organs are transported from the establishment, for example in a living donor pooled donation, the establishment contact NHSBT to arrange transport of the organ on their behalf. Where the establishment's NORS team have retrieved organs and are bringing them back to the establishment for implantation, the NORS team travel with the organ and would report any serious adverse events either at the time or upon arrival at the establishment.	**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 establishment has adopted NOP002 which contains details of who is responsible for verifying that the information in Annex A and B of the Directive is verified prior to implantation. The implanting surgeon is responsible for verifying this information. NOP002 is further strengthened by the use of two high level process flow sheets developed by the establishment. These two documents (Donor Characterisation Process' and 'I1+CT6 operating procedure') set out the process by which donor characterisation data is collected and communicated to the implanting surgeon who, only upon receipt of all clinical information, will accept or decline an organ. Advice given to the establishment under assessment criterion CT6 with regards to amendments to the 'Kidney/Pancreas Donor Offer Form' will also further strengthen the establishment's process for verification of donor characterisation data. The suggested amendments to the form will act as a record that the implanting surgeon has received the required information. Advice has been given to the establishment below with regards to amending NOP002 to reflect the use of all relevant forms and flow charts which are not currently reflected in the document.	**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. Transportation documentation and slush ice levels within the transport box are checked upon receipt of the organ at the establishment. These checks are recorded on the 'Kidney/Pancreas Received for Transplantation' form that has been developed by the establishment. Additionally this form is used to record the time and person receiving the organ at the establishment along with other details such as when slush ice levels are checked on an on-going basis.	**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 establishment indicated that should any of the information specified in Annex A of the Directive not be available then a risk/benefit analysis would be undertaken by the implanting surgeon and where appropriate discussed with the recipient. This analysis and discussion would be recorded in the recipient's clinical notes. Additionally, during a review of recipient's clinical notes, examples were found where risk/benefit analyses were undertaken as a result of the donor characterisation data which were available. The data, risks and benefits were discussed with the recipients who consented to proceed with implantation. In each case, the discussions with the recipients were recorded in the recipient's clinical notes.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has adopted NOP006 which states the requirement to return HTA A and B forms to NHSBT and the timeframe. The establishment tracks the return of HTA B forms via an excel spread sheet. The HTA was advised during the audit that a similar system will be set up to monitor the return of the HTA A forms for living donors. Although this standard is considered to have been met, advice regarding the revising of NOP006 to reflect the use of the excel tracking sheets has been given below.	**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.	**None**
TC3) A record (date and time) of the transportation of organs arriving at and/or leaving the establishment is kept for 30 years as part of the traceability information.	This criterion is fully met. Refer to I3.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Serious adverse events and reactions (SAEARs) – (*these criteria apply to all licensed activities*)		
S1) Operating procedures are in place for the management of a serious adverse event or a serious adverse reaction.	This criterion is fully met. The establishment uses the Trust's in house adverse event/incident reporting system to capture adverse events. Additionally, the establishment has adopted NHSBT's operating procedure SOP3888/1 for online reporting of serious adverse events and reactions to NHSBT.	**None**
S2) Serious adverse events and reactions are reported to NHSBT within 24 hours of discovery, a follow-up report is provided within 90 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. Refer to S1	**None**
S3) Third parties, such as those undertaking testing or transportation, are instructed to report any serious adverse events and reactions to the licence holder within 24 hours of discovery.	This criterion is not applicable. The establishment indicated that they do not hold a contract for the transportation of organs with any transport companies. Refer also to TP5	**N/A**

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. During the audit evidence was provided of appraisals for surgical staff. The senior appraiser reviews competence of staff. Records of competency sign off to undertake laparoscopic retrievals was also reviewed. Finally, NORS team competency sign off for liver retrievals by the establishment's NORs partner organisation were also reviewed.	**None**

GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.	This criterion is fully met. Refer also to GN1 The audit team was informed that a new competency based induction for transplant coordinators is being developed with the intention of implementing new competency assessments in the near future.	**None**
GN3) Medical activities are performed under the advice and guidance of a registered medical practitioner, and there are operating procedures in place to demonstrate this.	This criterion is fully met. Transplant activity is overseen by consultant-level staff. The establishment has also adopted National Operating Procedure 005 'Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation'.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	The establishment uses a 'Live Renal Donor Health History Questionnaire' and an 'Integrated Care Pathway for Living Kidney Donor' booklet to collect living donor and living donor organ characterisation information. The establishment has adopted NOP001 and the Licence Holder is advised to amend this document further to reflect the use of the above two documents so that the procedure mirrors the establishment's practice.
2.	CT5	The Licence Holder is advised to keep the CPA accreditation status of the serology testing laboratory under review so that the licence holder and HTA can be made aware when full accreditation has been achieved.
3.	CT6	The Donor Offer Form contains a call check list to help the recipient coordinator ensure that all of the necessary information has been provided, however, there is no way of logging that the key donor and organ characterisation data has been transmitted to the implanting surgeon. The licence holder is advised to review the donor offer form and to include a means by which a documented record can be generated to demonstrate that donor and organ characterisation data has been passed to the implanting surgeon.
4.	R4	The licence holder is advised to amend the wording of the referral letter sent to living donor's clinician to include a reminder that the donor's clinician should alert the establishment to any new indications in the donor that may have implications for the organ recipient.
5.	TP1	The establishment have developed a flow sheet which contains details on how to pack kidneys into the device ready for transportation using a hypothermic

		perfusion device. The licence holder is advised to incorporate this flow sheet into the amended version on NOP003 so that all organ transportation and packing procedures are reflected in the establishment's documents.
6.	I1	The establishment has strengthened NOP002 by the development of two high level process flow sheets. These two documents (Donor Characterisation Process' and 'I1+CT6 operating procedure') set out the process by which donor characterisation data is collected and communicated to the implanting surgeon who, only upon receipt of all clinical information, will accept or decline an organ. The Licence Holder is advised to update NOP002 to include all of the documents used to reflect the processes involved in the verification of the donor data and information contained in Annex A and B of the Directive.
7.	TC1	The establishment monitors and tracks the return of HTA B forms via an excel spreadsheet. The Licence Holder is advised to continue with plans to adopt a similar system to monitor the return of the HTA A forms for living donors. Additonally the Licence Holder is advised to amend NOP006 to reflect the use of the excel tracking sheets and include details of the required timeframes and which members of staff have responsibility for monitoring and returning the forms.

Concluding comments

During the audit evidence was seen that the establishment has reviewed its compliance with the Regulations. The establishment has taken a pro-active approach to governance and has undertaken reviews of the NOPs to assure itself that all areas of activity are reflected in the procedures. Where this has not been the case, additional documents describing process flows have been produced, which require referencing within the NOPs which have been adopted by the establishment.

The establishment also undertakes a review of all kidneys that are refused. The learning from these reviews is used to inform future strategies on organ acceptance and to determine if more organs may be suitable for use in transplant.

Advice has been given to the establishment with respect to various procedural documents.

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

Report sent for factual accuracy: 20 June 2013

Report returned with comments: 24 June 2013

Final report issued: 12 July 2013

Appendix: Classification of the level of shortfall

Where the HTA determines that an assessment criterion is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an assessment criterion, it works on the premise that a lack of evidence indicates a shortfall.
The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to the quality of an organ intended for transplantation or which poses a significant direct risk of causing harm to a donor or recipient.
Or
A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.
A shortfall in the carrying out of licensable activities which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient
or
A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the quality and safety of an organ intended for transplantation or which poses an indirect risk to the safety of a donor or recipient;
or
A shortfall which indicates a major deviation from the **Human Tissue (The Quality and Safety of Organs Intended for Transplantation) Regulations 2012** or the **Documentary Framework for the Quality and Safety of Organs Intended for Transplantation**;
or
A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting quality and safety of an organ intended for transplantation or the safety of a donor or recipient;

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final audit report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next audit.
In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final audit report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final audit report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.
Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit audit.

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