Site visit audit report on compliance with HTA requirements

NHS Lothian

HTA licensing number 40024

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

21 – 22 May 2013

Summary of Audit findings

NHS Lothian (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 (Quality and safety (organs) regulations) 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	
Heart	**DC, OC, P, T, R**
Kidney	**DC, OC, P, T, R**
Liver	**DC, OC, P, T, R**
Lung	**DC, OC, P, T, R**
Pancreas	**DC, 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	**OC, P, T, I**
Liver	**OC, P, T, I**
Pancreas	**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

The transplant unit at the establishment is based at the Royal Infirmary of Edinburgh (RIE). The establishment carries out both organ retrieval and transplantation activities with organs from adult deceased and living donors.

The Scottish Organ Retrieval Team (SORT) is based at the Royal Infirmary of Edinburgh. The team provides a multi-organ retrieval service. The Golden Jubilee National Hospital contributes a surgeon for retrieving cardiothoracic organs. The Royal Infirmary of Edinburgh provides the rest of the team, all equipment and preservation fluids.

The establishment has living liver and kidney programmes. While procedures are in place for the living liver programme, due to clinical reasons, the establishment has not completed any living liver transplants since the implementation of the Quality and Safety (Organs) Regulations. The living kidney programme is active and the establishment completes around 40 living cases a year. The transplant coordinators only accept transplant referrals directly from donors: referrals include directed and altruistic donations.

The establishment carries out around 90 deceased liver transplants a year and approximately 90 deceased kidney transplants. The kidney transplants include around 16 simultaneous kidney / pancreas transplants. The establishment also carries out the occasional pancreas-only transplant.

The audit included discussions with the Perioperative Lead, a transplant surgeon and transplant coordinators, a tour of the premises to observe the organ pathway through the establishment, a review of patient notes, document review and observation of a live kidney transplant.

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. Although this criterion is not applicable, on arrival, the retrieval team meet with the SN-OD to review all the donor and organ characterisation information.	**None**
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 Standard Operating Procedure (SOP)v1:011212 *Liver Transplant Coordinators* and SOPv1:011212 *Renal Transplant Coordinators* in place. This was cross-referenced with the National Operating Procedures (NOPs) created by NHS Blood and Transplant (NHSBT) to ensure all mandatory information is collected on a form. The *Referral of pancreas / kidney transplant form* provided further evidence that all mandatory information is collected prior to implant. For deceased donors, information is collected using NHSBT's electronic offer system (EOS).	**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. Refer to CT2.	**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 has SOPv1:011212 *Liver Transplant Coordinators* and SOPv1:011212 *Renal Transplant Coordinators* in place. This was cross-referenced with the NOPs created by NHSBT to ensure the HTA A Form, EOS data hard copy, blood group form, surgical / operative data form, the liver transport form (including the final use / destination of the organ) and the HTA B form copies are retained for 30 years from the date of retrieval of the organ.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. SOPv1:011212 *Liver Transplant Coordinators* and SOPv1:011212 *Renal Transplant Coordinators* states that only laboratories with Clinical Pathology Accreditation (CPA) are used. The establishment uses its own CPA-accredited laboratory and staff advised any adverse incidents would be reported to the Recipient Coordinator.	**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. The Scottish Organ Retrieval Team (SORT) Protocol states the lead retrieval surgeon will communicate with the lead implanting surgeon if there are important pre-operative, intra-operative or post-operative findings. Communication between the retrieving and implanting surgeons was observed during a living kidney transplant.	**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 SORT Protocol describes the pre-retrieval process. Prior to the retrieval process the surgeon reviews all documentation with the SN-OD, including authorisation documents. The FRM4135 is completed and the pre-operative safety checklist records that authorisation is in force. The *RIE Protocol for receipt of organs for transplantation* v01/12/12 states that permission for use in teaching and research is recorded on EOS and will have been communicated by researchers. Consent for living donors is taken by trained staff in stages and is documented.	**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. This is agreed with the supplier through the contract and tender process. For example, a contract stated: "All components and packs must comply with relevant European or equivalent standards and / or CE marking requirements." While the criterion is met, the establishment should note it, rather than the supplier, has the responsibility to ensure material and equipment meet the requirements. Advice is provided below.	**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 uses its Hospital Sterilising and Disinfection Unit (HSDU) to clean and sterilise reusable instruments. The HSDU has a validation certificate for its sterilisation and disinfection processes, registered with the British Standards Institute (Certificate number: MD81674).	**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. Endeavours are made to follow-up living donors. Living donors are provided with discharge letters and thorough follow-up based at the establishment. The living donor coordinators lead annual living donor follow-up clinics. The coordinators recently completed a questionnaire to confirm donor satisfaction with the establishment's existing follow-up arrangements. The *Living Liver Protocol* states that following discharge, the establishment will contact the donor's general practitioner to outline the procedure and provide details about emergency contacts. While the establishment has made endeavours to ensure it is able to follow up a living donor for the purposes of identifying and managing relevant events, there is no specific alert given about reporting events. Advice is provided below.	**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. SOPv1:011212 *Liver Transplant Coordinators* and SOPv1:011212 *Renal Transplant Coordinators* require preservation fluid name and batch number to be recorded.	**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. Organs are triple-bagged with preservation fluid under sterile conditions during organ retrieval and using melting water ice, according to the National Organ Retrieval Service Guidelines. This is supported with the *RIE Organ Retrieval Protocol*. This practice was observed during a living kidney transplant to transport the organ between theatres. On this occasion, the kidney was triple-bagged to ensure preservation during a slight time delay before implant into the recipient. Advice is provided below.	**None**
TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The establishment uses a range of transport boxes. The establishment also uses two portable kidney preservation machines for organs retrieved after circulatory death. It has an identification system in place on the outside of the machine, to ensure differentiation between left and right kidneys. The *Retrieval Protocol* requires organs to be placed in an appropriate-sized box. The establishment continues to maintain standards in line with advice from NHSBT.	**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. The *Retrieval Protocol* states the SN-OD completes the organ transport form, FRM4217 which travels with the organ.	**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 *Retrieval Protocol* requires organs to be packed with a copy of the organ-specific “A” form and a copy of the donor blood group.	**None**

TP5) Arrangements are in place to ensure that any organisations transporting organs on behalf of the licence holder meet the requirements for transportation and serious adverse event and reaction reporting specified in the framework document.	This criterion is fully met. The establishment has a service level agreement (SLA) in place with its transport provider. This includes a requirement of the need to report, especially if there are problems with the integrity of the packaging. This was supported by an email from the transport company confirming its staff are aware of the need to report incidents.	**None**

Assessment Criteria	**Audit findings**	**Level of Shortfall**
Implantation		
I1) The identification of the donor and the collection of the information in Annex A and B of the Directive are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The SORT Protocol states the lead retrieval surgeon will communicate with the lead implanting surgeon if there are important pre-operative, intra-operative or post-operative findings. Communication between the retrieving and implanting surgeons was observed during a live living kidney transplant.	**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 *RIE Protocol for Receipt of Organs for Transplantation v1 01/12/12* requires ward staff to check kidneys and keep ice topped up. Deceased donor livers are accepted into theatre immediately on arrival. Theatre staff check the documents and organ box.	**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. A transplant surgeon explained that the risk-benefit analysis is an ongoing process at all stages of the recipient's treatment at the establishment. Discussions to assess risk are documented in the patient notes.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
Traceability – (*these criteria apply to all licensed activities*)		
TC1) The data required to ensure traceability of organs are recorded using the HTA A and B forms, which are returned to NHSBT within 7 days, and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. SOPv1:011212 *Liver Transplant Coordinators* and SOPv1:011212 *Renal Transplant Coordinators* and the SORT Protocol all require return of the HTA A and B Forms within seven days by the Transplant Coordinator.	**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. The establishment uses name, date of birth, Community Health Index (CHI) numbers and hospital numbers to identify patients and organs. The establishment also uses a *Kidney / Pancreas Receipt Form* to confirm the organ and donor details. Two of the establishment's data capture forms were observed during the audit that contained a CHI number rather than a hospital number in the relevant field on the form. This did not affect traceability of the information. Advice is provided below.	**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. SOPv1:011212 *Liver Transplant Coordinators* and SOPv1:011212 *Renal Transplant Coordinators* requires all traceability information, including the records of organs arriving and leaving the organisation for 30 years. Records are kept by the transplant coordinators in a secure office.	**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 SOP 3888 written by NHSBT has been adopted as *RIE serious adverse events and reactions (SAEARs) Operating Procedure* v1 011212 *Reporting organ donation or transplantation incident to NHSBT.* This document has been circulated to all staff. SOPv1:011212 *Liver Transplant Coordinators* and SOPv1:011212 *Renal Transplant Coordinators* includes a requirement that any records associated with SAEARs should accompany the organ.	**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 fully met. The establishment uses its own CPA accredited laboratory. The transport company is instructed to report incidents and this requirement is governed by an SLA.	**None**

Assessment Criteria	Audit findings	Level of Shortfall
General – (*these criteria apply to all licensed activities*)		
GN1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are competent and suitably qualified or trained to perform their tasks.	This criterion is fully met. Higher Surgical Trainees are required to maintain full General Medical Council (GMC) registration, complete the Membership of the Royal College of Surgeons (MRCS) exam, undertake a regular performance review, maintain a log book and undertake ongoing assessment. During the audit evidence was seen of Higher Surgical Trainees confirming GMC registration and MRCS through signed statements. Consultant Surgeons are required to maintain full registration and undergo regular review. Operating theatre staff are required to be registered with their relevant body and undergo regular performance reviews.	**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 Perioperative Lead maintains a competence matrix to develop the rota for on-call staff and identify training needs. The Perioperative Lead formally assesses staff as required to ensure staff have attended enough retrievals to maintain their competence. For example, reviewing competence when staff return to work after long-term leave. The Perioperative Lead also maintains a *Retrieval Data Capture Form* to track the number of staff retrievals and uses this to inform formal performance appraisals.	**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 responsibility for oversight by the lead surgeon is embedded in the establishment's protocols.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	R2, P1	The establishment ensures it uses equipment and material that meet the requirements of the Medical Devices Regulations 2002. The responsibility is placed on the supplier to ensure all material is CE marked, through contracts and tenders. The establishment should remain aware that the responsibility to ensure material is appropriate lies with the establishment. The establishment is advised to update its procurement policy to require procurement of medical equipment and material that meet the requirements.
2.	R4	The establishment makes endeavours to follow-up its donors after transplants in a number of ways, including through follow-up clinics. Although donors routinely contact the establishment with any problems, the establishment is advised to review its method of ensuring donors are aware of reporting requirements. For example considering including information in a discharge letter to ensure references to reporting serious adverse reactions that may be related to the donation, or may affect the recipient, are clearly articulated.
3.	TP1	The establishment has the *RIE Protocol for Receipt of Organs for Transplantation v1 01/12/12* in place. This states, “organs declined for transplantation will be re-packaged.” The establishment is advised to elaborate on this instruction to ensure re-packaging requirements are clear for staff in this situation.
4.	TC2	While all information was fully traceable, there were inconsistencies observed on two forms, where hospital numbers were written in the CHI number field. Although this did not affect traceability, the establishment is advised to monitor the standard entry of information, for example, through auditing forms.

Concluding comments

There were a number of areas of good practice observed during the audit. The establishment had completed an internal audit against all of the HTA criteria, to ensure it had the necessary documentary evidence available. The establishment had also produced written summaries of its compliance with each criterion.

The establishment maintains strong communication across all people involved in transplant. The transplant coordinators keep good records of all traceability data and had a caring and knowledgeable approach when describing their patient interactions.

The audit team was particularly appreciative of the opportunity to observe a live kidney transplant, on the establishment's invitation and with patient knowledge. This allowed the team to observe written protocols being followed in practice and to note the strong communication links between retrieval and transplant staff.

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

Report sent for factual accuracy: 21 June 2013

Report returned with comments: 12 July 2013

Final report issued: 16 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.