Site visit audit report on compliance with HTA requirements

Greater Glasgow and Clyde Health Board

HTA licensing number 40022

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

20 August 2013

Summary of Audit findings

Greater Glasgow and Clyde 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

Adult living	
Kidney	**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

Adult and Paediatric – living and deceased	
Kidney	**OC, P, T, I**

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

Background to the establishment and description of audit activities undertaken

The establishment's licence extends to adult procurement of living kidneys and implantation of deceased and living donor kidneys at the Western Infirmary and implantation of paediatric living and deceased donor kidneys at the Royal Hospital for Sick Children (Yorkhill). The service is consultant-led, with support from registrars, transplant coordinators and other ward and theatre staff. The establishment has experienced an increased involvement with altruistic and paired / pooled donations. In the previous year the establishment implanted approximately 100 deceased kidneys and carried out approximately 40 living kidney transplants, five to 10 of which were paediatric living cases.

When a living adult kidney, retrieved at the establishment, is destined for implantation at Yorkhill it is accompanied by the retrieving surgeon. Responsibility for external transport, for example in the case of reoffer, donation to research, altruistic or paired / pooled donations is managed by NHS Blood and Transplant (NHSBT). The establishment packages the organs according to a protocol and keeps a record of all organs arriving and leaving the establishment.

The establishment conducts living adult transplants in one operating theatre. In the time between the retrieval and implantation operations, the kidney remains in the theatre. Preservation fluid is maintained in theatre and is subject to daily checks to ensure stocks are within the correct expiry dates. At Yorkhill, preservation fluid is ordered from the hospital pharmacy as needed.

For deceased kidneys, offers are received by the on-call registrar who liaises with the consultant surgeon through NHSBT's electronic offer system (EOS). The surgeon reviews the information and the complete record is subsequently printed for easy reference. This is kept on file. If an offer is accepted, the donor kidney arrives at the renal service ward and is accepted by the ward manager on duty. The kidney is stored in a secure room. A ledger is completed to ensure integrity of packaging has been ascertained and slush ice levels are correct. The establishment's laboratory staff are contacted to collect the lymph nodes and spleen for testing. This is also recorded in the ward ledger. Once the kidney is taken to theatre, this is also noted on the ward ledger and on a theatre ledger. Integrity is checked again at theatre and the surgical team physically check the organ.

This was the establishment's first, routine audit. The audit encompassed a visual tour of the premises at the Western Infirmary and Yorkhill, document review, round table discussion with the renal team and traceability audit. The traceability audit involved cross-referencing details of a living adult donor to a child recipient, through to review of patient notes. Three patient files were reviewed to determine the presence of traceability records, operation notes and related documentation, and copies of the relevant HTA A and B forms and EOS printouts were located. Only minor typographical anomalies were found in relation to the telephone record of one donor offer.

The establishment is also developing a potential facial transplant programme. A discussion was held with members of the maxillofacial team and general manager to discuss licensing requirements. As the service is not currently active, this programme was not assessed against the audit criteria.

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 *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP001 Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation* in place. One set of living donor patient notes was reviewed which did not have history of intravenous drug use specifically recorded. Advice is provided.	**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. The establishment has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP001 Donor and organ characterisation, assessment and allocation in deceased and living donation and transplantation* in place.	**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 *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure:NOP006 Transfer and storage of donor and organ characterisation information and storage of traceability data* in place. All transplant folders are stored in the transplant coordinators' office. EOS copies are kept on file. The Board's record retention policy, *001 Procedure for retention, destruction and archiving of health records* does not specifically mentions transplant traceability data. Advice is provided below.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. The laboratories used by the establishment have clinical pathology accreditation (CPA)	**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 establishment has a consultant-led service. The consultant surgeon receives the information from the NHSBT duty office and reviews the data on the EOS. This is printed and retained on the file for easy reference. The retrieving surgeon is part of the implanting team and the operation includes a surgical pause to check on certain key information.	**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. Consent is a staged process. Transplant coordinators and consultants are involved throughout the process, before an independent assessment.	**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 has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP004 Management of procurement material and equipment in deceased and living donation and transplantation* in place. Everything used by the hospital is CE marked, however the Board's procurement strategy does not specifically mention regulatory compliance. Advice is provided.	**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 has a Central Decontamination Unit (CDU). The Lloyd's Register Quality Assurance (LRQA) Business Assurance Certificate of Approval was observed for: CDU, NHS Greater Glasgow quality management system approved by LRQA to quality management system standards: ISO13485: 2003. The approval certificate number was: LRQ4002546 and applied to disinfection, assembly and sterilisation of reusable theatre ward and department instrumentation and supplementary items in accordance with the requirements of the European Medical Device Directive 93/42/EEC. *7.4.22 Work instructions for the return of vCJD contaminated instrumentation to the CDU* was also observed.	**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. Donors are offered follow-up appointments at regular intervals for the first year after the transplant. While donors are followed up and can contact the establishment, specific reference is not made to reporting any incidents that may affect the recipient. Advice is provided.	**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. The establishment records perfusion fluid name and batch number on HTA A and B forms. The establishment also records this information on its electronic patient record system and on its theatre ledgers.	**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 has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP003 Packaging, labelling and transport of organs in deceased and living donation and transplantation* in place. The receiving areas have a *Protocol for receiving and transporting detained donor kidney tissue typing sample* on display. When organs are received into the ward the integrity of the packaging and ice levels are checked and recorded in a ward ledger. The paediatric transplant centre uses *Guidelines on management of paediatric transplant*, which includes information on receipt procedures.	**None**

TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. As above. The establishment uses NHSBT kidney organ boxes.	**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 establishment has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP003 Packaging, labelling and transport of organs in deceased and living donation and transplantation* in place. The establishment uses NHSBT kidney organ boxes.	**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 establishment has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP003 Packaging, labelling and transport of organs in deceased and living donation and transplantation* in place. The establishment uses a ward ledger for integrity checking, this could be used further for ensuring the organ is accompanied by documentation. Advice is provided below.	**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. All external transport providers are contracted by NHSBT. Occasionally, the establishment procures an adult living organ for transplant at the paediatric unit at Yorkhill. In these cases the organs are accompanied by the transplant surgeon.	**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 establishment has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP002 Verification of donor identity, consent / authorisation and organ and donor characterisation in deceased and living donation and transplantation* in place. There is a surgical pause during the transplant to ensure relevant information is in collected. Advice is provided below.	**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 check the conditions of preservation and transport as soon as the organ is received. These checks are recorded in the ward ledger. The integrity is checked again before transplant and recorded in the theatre ledger. The organ is physically examined by the surgical team before implantation.	**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. Risk benefit analyses are recorded in patient notes. Evidence was seen of a risk benefit analysis on the establishment's electronic patient record management system.	**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 *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP006 Transfer and storage of donor and organ characterisation information and storage of traceability data* in place.	**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 and community health index (CHI) number for donors and recipients. For deceased organs the establishment uses the donor organ donation and transplantation (ODT) number, date of birth, hospital identification / CHI number. For living organs the establishment uses the donor name, date of birth and hospital identification / CHI number.	**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. The establishment has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP006 Transfer and storage of donor and organ characterisation information and storage of traceability data* in place. The Board policy, *001Procedure for retention, destruction and archiving of health records* does not specifically mention retention periods for transport records related to transplant. Advice is provided.	**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 has *SOP3888/1 Reporting an organ donation or transplantation incident to NHSBT.* The establishment also has a *Policy on the management of significant clinical incidents* in place. This requires all incidents to be logged on the Board's electronic incident reporting system.	**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. As above.	**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 laboratories used by the establishment use the internal incident reporting system. External transport is provided by NHSBT and when organs are sent to the paediatric unit they are accompanied by a surgeon, who is aware of the need to report incidents.	**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. The establishment has adapted the *NOP005 Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation* to include two supplements: *Supplement one: assumptions of competency and documentation of competency* details the assumptions made about the competency of staff involved in transplant surgery, anaesthesia and theatre nursing. *Supplement two: log of qualified staff for the purposes of organ donation and transplantation* lists names of staff involved in transplant activities and General Medical Council (GMC) numbers, details of the latest Board appraisal, GMC revalidation date and specialist register date. In the case of nursing staff, Nursing and Midwifery Council (NMC) numbers and Knowledge and Skills Framework sign-off is included.	**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. All staff are subject to formal appraisal procedures. Transplant coordinators complete a Renal Competence Framework. This includes completion of: • *RenLDI Assess the health and suitability of a prospective living organ donor;* • *RenLD2 Enable potential living organ donors to decide whether or not to donate;* • *RenLD3 Prepare the living organ donor for admission;* • *RenOP2 Enable patients and their families to understand established renal failure and its treatment;* • *RenOP4 Foster multidisciplinary team working; and* • *RenOP5 Provide psychological support for members of the multidisciplinary team.*	**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 has *NHS Greater Glasgow and Clyde – Renal transplant National Operating Procedure: NOP005 Activities to be performed under the guidance of a registered medical practitioner in deceased and living donation and transplantation* in place.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	CT2	The mandatory data set is collected, however one of the living donor files reviewed did not show evidence that history of intravenous drug use is taken. This may be asked but not specifically recorded. The establishment is advised to consider putting systems in place to ensure all mandatory data is available, for example patient questionnaires or checklists for use by transplant coordinators to record all the necessary information in one place.
2.	CT4, TC3	The establishment has adapted *NOP006 Transfer and storage of donor and organ characterisation, information and storage of traceability data*. The Board's *Procedure for retention, destruction and archiving of health records* references storage periods for certain record types. This document does not specifically refer to retention periods for organ and donor characterisation or transport records for transplant. The establishment should consider amending this policy for consistency.
3.	R2, P1	The establishment has adapted *NOP004 Management of procurement material and equipment in deceased and living donation and transplantation*. In addition, all material in the hospital is CE marked, however the Board's procurement strategy does not specifically mention the need to use material and equipment that meets the requirements of the Medical Devices Regulations 2002. The establishment should consider amending the strategy for consistency.
4.	R4	The establishment gives its living donors the option of several follow-up appointments for 12 months and donors are given a discharge letter on release to their treating doctor. The communication given to the donor does not explicitly mention the need to report any subsequent serious adverse events or reactions that may affect the recipient. The establishment is advised to review its discharge processes and ensure references to reporting serious adverse reactions that may affect the recipient are clearly articulated.
5.	TP4	The establishment uses a ward ledger to record, date and time of arrival, the person delivering the organ and identification checks, person receiving the organ, tag number, integrity (box and ice levels), tissue typing samples are sent and details about the organ leaving the ward. This could be extended to include a check that the accompanying paperwork has been received with the organ.
6.	I1	The establishment uses a surgical pause to check key characterisation information. The surgical pause could be adapted further to include a check that all or any updated information has been taken and verified.
7.	N/A	While the establishment has adopted and adapted the NOPs, it is advised to consider ensuring that adopted procedures are reflective of practice and continue to review the NOPs. For example, the paediatric transplant centre uses *Guidelines on management of paediatric transplant*. This is a detailed protocol on both clinical procedures and traceability measures, which could guide further development of adapted NOPs.

Concluding comments

There were areas of strength and good practice observed during the audit. The establishment has developed its own documents such as protocols, flowcharts and ledgers in addition to adopting and adapting national operating procedures. Traceability of an organ is maintained through thorough receipt checks when an organ is accepted on the ward, through to implantation. To further support traceability, the establishment has an electronic patient records management system in use across the health board. Staff spoke positively about the user-friendly interface, which is more likely to encourage widespread uptake and accurate record-keeping. Evidence was seen that this is regularly updated and a widely used resource. This system also allows for traceability between the establishment's adult and paediatric transplant centres.

The HTA has given advice to the establishment with respect to collection and verification of mandatory data, records retention, medical equipment procurement policies, follow-up of living donors, documentation of receipt procedures and continual review of procedures to ensure compatibility with actual practices.

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

Report sent for factual accuracy: 12 September 2013

Report returned with comments: 4 October 2013

Final report issued: 4 October 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.