**Site visit audit report on compliance with HTA requirements**

**Newcastle upon Tyne Hospitals NHS Foundation Trust**

**HTA licensing number 40045**

**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**

**26-28 March 2013**


**Summary of Audit findings**

Although the HTA found that Newcastle upon Tyne Hospitals NHS Foundation Trust (the establishment) had met the majority of the assessment criteria, three minor shortfalls were found in relation to the absence of documented operating procedures for relaying donor and organ characterisation information to the implanting surgeon, and for the return of HTA A and B forms to NHSBT within seven days.

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 | Heart | Lung | Liver | Kidney | Pancreas |
|---|---|---|---|---|---|
| **Adult living** | **-** | **-** | **-** | **DC, OC, P, T, R** | **-** |
| **Adult deceased** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **-** | **DC, OC, P, T, R** |
| **Paediatric deceased** | **-** | **DC, OC, P, T, R** | **DC, OC, P, T, R** | **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 | Heart | Lung | Liver | Kidney | Pancreas |
|---|---|---|---|---|---|
| **Adult** | **OC, P, T, I** | **OC, P, T, I** | **OC, P, T, I** | **OC, P, T, I** | **OC, P, T, I** |
| **Paediatric** | **OC, P, T, I** | **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

Newcastle upon Tyne Hospitals NHS Foundation Trust (the establishment) is a multi-organ centre, which carries out cardiothoracic and abdominal organ transplantations for adult and paediatric patients. Transplants are performed at the Freeman Hospital for all adult patients and for paediatric heart recipients. Kidneys for paediatric recipients are implanted at the Royal Victoria Infirmary.

Upon arrival at the establishment, cardiothoracic organs are taken directly to theatres, abdominal organs could also be received on a ward prior to being taken to theatres.

The establishment provides staff to abdominal and cardiothoracic National Organ Retrieval Service (NORS) teams. As well as UK retrievals, the cardiothoracic NORS team will, in a small number of cases each year, retrieve hearts and lungs from paediatric donors in mainland Europe.

Tissue typing and cross-matching are performed on behalf of the establishment by an NHS Blood and Transplant (NHSBT) histocompatibility and immunogenetics (H&I) laboratory based in Newcastle. Other characterisation tests for living donors, and any additional characterisation tests on organs from deceased donors as necessary, are performed by the establishment's virology and histopathology laboratories. Transportation of organs is carried out by a specialist courier company on the establishment's behalf, or by an NHSBT-commissioned courier for nationally allocated kidneys.

## Compliance with HTA assessment criteria

| Assessment Criteria | Audit findings | Level of Shortfall |
|---|---|---|
| Donor Characterisation and Organ Characterisation | | |
| CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information. | The establishment 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 is applicable for living donors.<br>This criterion is fully met.<br>Donor and organ characterisation information is gathered during work-up for living donors. | **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.<br>Additional characterisation tests on an organ from a deceased donor will normally be performed at the retrieval hospital, but could as necessary be performed at the establishment's laboratories upon receipt of the organ.<br>In living donation cases, where circumstances require them, additional tests are carried out as required 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.<br>Staff gave verbal assurance during the audit that all records relating to transplantation will be kept for thirty years in a defined location within the establishment .<br>The 'Clinical Records Management Policy' states that the retention period for records of deceased persons is 8 years after death, which is the period given in the NHS Code of Practice on Records Management Part 2 (second edition) Annex D1. The auditors were told this Trust policy is to be updated to state that all transplant records must be kept for thirty years from the date of retrieval of the organ.<br>*The HTA has given advice against this criterion.* | **None** |

| | | |
|---|---|---|
| CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation. | This criterion is fully met.<br><br>The full CPA accreditation status of the NHSBT H&I laboratory, and of the establishment's virology and histopathology laboratories, was verified with the CPA website. | **None** |
| CT6) Information on organ and donor characterisation reaches the person who will be implanting an organ within a time period that would not compromise the quality and safety of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with. | This criterion is almost met.<br><br>Characterisation information for living donors is gathered during work-up. The retrieving and implanting surgeons discuss donor and organ characterisation information prior to implantation.<br><br>The on-call recipient coordinator receives a phone call from NHSBT Duty Office when an organ from a deceased donor is offered. The recipient coordinator prints out, or transcribes onto a 'Donor Record Form', donor information from NHSBT's Electronic Offering System (EOS) and relays this information to the implanting surgeon in person or may, if outside normal working hours, do this by phone. A surgeon may, as required, request further details from the SN-OD before provisionally accepting an organ which has been offered.<br><br>Details of phone calls between the retrieving and implanting surgeons, SN-OD and recipient coordinator during retrieval are transcribed by the recipient coordinator onto the 'Retrieval Record'.<br><br>The implanting surgeon verifies donor information on the HTA A form when an abdominal organ is received, for cardiothoracic organs the recipient coordinator usually does this.<br><br>Occasionally, an organ may be sent to another centre for implantation. This could occur, for example, with an altruistic donor kidney or if a deceased donor kidney is declined upon receipt, and is re-offered into the national pool. In such cases, and as described above for organs from deceased donors being received by the establishment, procedures to ensure the implanting surgeon receives organ and donor characterisation information from the recipient coordinator prior to implantation are well established and effective. However, these procedures have not been documented.<br><br>*Refer also to criterion TP4.* | **Minor** |

| 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.<br>For deceased UK donors, consent is sought by a SN-OD under NHSBT's licence. Consent for procurement from a living donor is sought by the retrieving surgeon.<br>The donor consent form is reviewed by the retrieving surgeon during the pre-operative surgical pause. | **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.<br>The 'Medical Devices Management Policy' cites the Medicines and Healthcare products Regulatory Agency's (MHRA) 'Managing Medical Devices' – DB2006(05) document, which in turn references the Medical Devices Regulations 2002. | **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.<br>Reusable instruments used in retrieval are sterilised at the establishment's central sterilisation and decontamination unit. The unit's accreditation certificate was reviewed at the audit. | **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.<br>Living kidney or liver lobe donors have a surgical review three months after discharge, which is conducted by the retrieving surgeon, with annual health checks thereafter. A donor may opt to have their annual health checks at the establishment, their local hospital or through their general practitioner (GP).<br>*The HTA has given advice against this criterion.* | **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.<br>The 'Medical Devices Management Policy' cites the MHRA's 'Managing Medical Devices' – DB2006(05) document, which in turn references the Medical Devices Regulations 2002. | **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.<br>Reusable instruments used in organ preservation are sterilised at the establishment's central sterilisation and decontamination unit. The unit's accreditation certificate was reviewed during the audit. | **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.<br>Details of perfusion fluids are recorded on the appropriate HTA A and B forms, and are also recorded in the operation notes, which are kept with the patient's records.<br>An audit of patient records for four cardiothoracic and four abdominal transplant procedures confirmed that perfusion fluid details were recorded on the HTA A and B forms. | **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.<br>Organs are transported within the UK, and for cardiothoracic retrievals from mainland Europe, by a specialist courier company.<br>The establishment uses NHSBT transport boxes for kidneys and for pancreases. The abdominal NORS team may also use Lifeport pods for kidneys retrieved from deceased after circulatory death (DCD) donors, when these organs are to be returned to the establishment for implantation. Livers, hearts and lungs are currently transported in proprietary cool boxes. The establishment will use NHSBT-approved transport boxes for these organs, when such boxes become available nationally.<br>Occasionally, an organ may be sent to another centre for implantation. This could occur, for example, with an altruistic donor kidney or if a deceased donor kidney, declined upon receipt, is re-offered into the national pool. In such cases, the establishment uses an NHSBT kidney box, which is packaged and labelled according to the accompanying instructions. Transportation is organised by the receiving centre. | **None** |
| TP2) The organ shipping container is suitable for transport of the specified organ. | This criterion is fully met.<br>Refer to criterion TP1. | **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.<br>At NORS retrievals the transport box is labelled by the SN-OD for an abdominal organ or, for a cardiothoracic organ, by the perfusionist.<br>If a kidney is to be sent elsewhere for implantation, the transplant coordinator labels the transport box in accordance with the labelling instructions provided with it. | **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 almost met.<br>Refer to criterion CT6. | **Minor** |

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| 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.<br>The courier company that transports organs on the establishment's behalf has been notified of the requirement for serious adverse event and reaction reporting. | **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.<br>The implanting surgeon verifies donor information from the HTA A form upon receipt of the organ.<br>The 'Cardiopulmonary Transplant Surgical Safety Checklist' specifically requires the transplant coordinator to give a verbal update to the implanting surgeon on the suitability of the organ.<br>*The HTA has given advice against this criterion.* | **None** |
| I2) Compliance with the conditions of preservation and transport outlined in the framework document are verified prior to proceeding to implant an organ. | This criterion is fully met.<br>The ice-slush level in the transport box, and the HTA A form, are verified upon receipt of an organ at the establishment. The checks are documented on the 'Organ Receipt' form. | **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.<br>Where any donor information is not available, a risk-benefit analysis is documented by the implanting surgeon in the recipient's clinical records. | **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 almost met.<br>While the process and requirement for returning HTA A and B forms to NHSBT within seven days is understood by staff, there is no documented procedure explaining how HTA A and B forms are collated and returned to NHSBT. | **Minor** |
| TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it. | This criterion is fully met.<br>Recipients and living donors are traceable by their name, hospital number and date of birth. Deceased donors are traceable through their NHSBT donor number, which is on EOS and on the HTA A form. | **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.<br>The date and time of arrival of an organ at the establishment are recorded on the 'Organ Receipt' form. Staff gave the auditors verbal assurance that these forms are kept for thirty years.<br>*The HTA has given advice against this criterion* | **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.<br>Serious adverse events and adverse reactions are managed within the Trust through Datix. 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.<br>The establishment has adopted NHSBT's operating procedure SOP3888/1 for online reporting of serious adverse events and reactions to NHSBT. | **None** |

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| 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.<br>Written evidence was seen during the audit verifying that the courier company transporting organs on the establishment's behalf is aware of this reporting requirement. | **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.<br>Healthcare personnel are registered with the appropriate professional regulatory body and undertake continuing professional development activities to maintain their registration.<br>New transplant coordinators and members of NORS teams receive induction programmes and undertake competence-based assessments. All staff have regular performance appraisals. | **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.<br>Refer to criterion GN1. | **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.<br>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. | CT4, TC3 | The establishment is advised that if updating the 'Clinical Records Management Policy' to state the requirement for all transplantation records to be kept for thirty years might take several months, then it should instead draft a local policy which states this requirement. The establishment is further advised |

| | | |
|---|---|---|
| | | that the thirty-year retention requirement applies to records of donor and organ characterisation, and of the receipt or release of organs, not a patient's full set of clinical records. |
| 2. | R4 | The establishment is advised to consider whether there is any additional information it may wish to provide to a living donor's GP, and the format of this information. For instance donors could receive, on a laminated wallet card, information on the tests which they should undergo on an annual basis, and that any serious adverse event or adverse reaction experienced by them which could derive from the organ donation, or which may have a potential impact on the recipient, such as developing a malignancy, should be reported to the establishment. |
| 3. | I1 | The establishment is advised to develop a transplant surgical safety checklist for abdominal transplantation, to mirror that used for cardiothoracic transplants, to incorporate the provision of an update for the implanting surgeon on donor and organ characterisation. |

## Concluding comments

Despite the minor shortfalls, several areas of strength were identified. The auditors were impressed by the commitment and knowledge of staff involved in transplantation, and by their excellent team working and communication. The establishment maintains meticulous records of traceability and communications throughout the transplantation pathway. The induction programmes, and competence-based assessments, for new transplant coordinators and for members of NORS teams are comprehensive.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the establishment with respect to some assessment criteria.

The HTA requires that the establishment addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the audit.

**Report sent for factual accuracy: 03 May 2013**

**Report returned with comments: 23 May 2013**

**Final report issued: 30 May 2013**

**Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the organisation has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Audit Report.

**Date: 04 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.