Site visit audit report on compliance with HTA requirements

Golden Jubilee National Hospital

HTA licensing number 40028

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 Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014.

15-16 March 2017

Summary of Audit findings

Golden Jubilee National Hospital (the establishment) was found to have met all assessment criteria.

The HTA has given advice to the establishment with respect to some procedural documents, checklists and communication with third party laboratories with respect to incident reporting.

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	Lungs
Adult deceased	**DC, OC, P, R**	**DC, OC, P, R**

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

Licensable activities carried out by the establishment – Transplant activities

Organ type	Heart
Adult	**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 Golden Jubilee National Hospital (the establishment) has been licensed by the HTA since December 2012 under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended by the Quality and Safety of Organs Intended for

Transplantation (Amendment) Regulations 2014. The establishment undertakes heart transplants and also participates in National Organ Retrieval Service (NORS) activity through which it retrieves hearts and lungs from deceased donors. The establishment undertook thirteen heart transplants in the previous year.

The establishment stores equipment and consumables for use in NORS retrievals in a dedicated area within the theatre complex. NORS retrieval kits and other equipment used during organ and donor characterisation such as endoscopes and ultrasound equipment are paced and stored ready to be taken should the NORS team be mobilised. Checklists have been produced for staff to follow when making up new NORS kits when they return from a retrieval. Perfusion fluids come from pharmacy and are stored in dedicated fridges within the storage room. These fridges have their temperatures monitored by establishment staff as part of the theatre critical equipment checks.

During the audit, validation records for the establishment's sterilisation equipment and accreditation of the sterile services quality management systems were reviewed. The central sterile processing department (CSPD) at the establishment was found to have met the requirements of the assessment criteria.

Bespoke procedures, for decontaminating and sterilising additional equipment used in donor and organ characterisation assessments such as endoscopes and ultrasound equipment, have been produced by the establishment, and were also reviewed. A specific procedure for cleaning and sterilising the trans-oesophageal ultrasound devices, following their use at the donor hospital before returning them, is in place and involves the use of a series of approved wipes. Endoscopes used for bronchoscopies are cleaned immediately following their use with an enzymatic solution and water. After this initial clean at the donor hospital, the endoscope is packed and returned to the establishments CSPD for cleaning and sterile packing prior to its next use. In summary decontamination and sterilisation procedures at the establishment for reusable equipment were suitable.

The establishment has adopted national operating procedure NOP004 which mandates that all equipment used in retrieval and transplantation must meet the requirements of the medical devices regulations. In addition, the establishment's Health Board has policies in place that state that any equipment purchased must meet the requirements of the medical devices regulations.

Staff involved in the establishment's licensable activities are suitably trained. Nursing staff undergo competency-based training when they join the transplant team. Practice is observed and, when appropriate, staff are signed off as competent to work independently. All staff must undergo the Health Board's annual mandatory training which covers areas including health and safety, fire training, and manual handling. In addition, there are regular continuous professional development days, which the establishment has used in the past to simulate being mobilised for a retrieval and undertaking retrievals. All staff including medical and surgical staff undergo regular appraisals, which incorporate feedback from colleagues. Surgical staff that undertake retrievals also undertake specific NORS training.

During the audit visit, the HTA auditors reviewed four sets of clinical notes of heart transplant recipients. In all four cases, the complimentary donor files were also reviewed and relevant traceability and checklist documents seen.

Documents reviewed in each case included HTA-A and HTA-B forms, transplant form used to record receipt of the organ, records of perfusions fluids used and ischaemic times, copies of EOS, tissue typing results (virtual cross matches and post transplant wet cross matches), cardiac transplant checklist forms, donor blood group form arriving with the organ and the establishment's verification of donor identity form. During the review of these documents, donor identifiers and blood group details were cross-checked and no anomalies were found. In one of the four cases a biopsy had been taken of a suspect lesion in the donor. The donor

referral form recorded that the surgeon had undertaken a risk benefit review of the suitability of the organ in light of the biopsy and that this had been discussed with the recipient. A review of the recipient's consent form demonstrated that the form had been amended to include details of the risk benefit analysis and that the recipient had consented to proceed with the transplant after having been made aware of any risks. In one case a 'verification of donor identity' form had not been fully completed as the box to signify that the surgeon was satisfied that the appropriate preservation conditions had been maintained throughout transport of the organ had been maintained; advice regarding this has been given below (see advice item 4).

Transplant

The initial organ offer from the NHSBT Duty Office is received by the on-call transplant coordinator (TC) who then logs into the electronic organ offering system (EOS) to review donor and organ characterisation information. Key characterisation information is sought and recorded by the TC onto a donor offer form. The TC may contact the SNOD at the donor hospital for further information at this stage or will otherwise contact the transplant surgeon with details of the organ offer. The surgeon reviews the characterisation data either within EOS, or from a copy of EOS, sent to them by the TC. This data is reviewed along with other information such as an echocardiogram and the donor and recipient tissue cross match information. The surgeon will liaise with surgical colleagues or a cardiologist to review the characterisation information before making a decision to accept or reject the organ offer. Other clinical and medical staff may also be involved in the acceptance process as required; for example, advice may be sought from a virologist. In summary, the establishment uses a multidisciplinary team approach to the assessing and acceptance of organ offers.

If any donor characterisation data indicates any potential risk associated with the organ or is not available at the time of the implantation, the implanting surgeon will undertake a risk benefit analysis, which is documented within the recipient's clinical notes. In addition, the implanting surgeon will discuss these issues with the recipient and seek their consent to proceed with the implant, having been informed of the issues.

If accepted the TC starts liaising with the NHSBT duty office and SNOD from the donor hospital to learn about the planned time of retrieval. In addition, the TC will start to organise theatre time at the establishment. The implanting surgeon will discuss the condition and appearance of the donor heart with the retrieving surgeon prior to the organ being retrieved and the recipient surgery commencing. Prior to recipient surgery starting, donor and recipient information is discussed during a surgical brief. In addition, function of the donor heart, cross match information, need for postoperative extra corporeal membrane oxygenation (ECMO) and any relevant recipient conditions are discussed.

The TC is alerted when the organ transport driver is approaching the hospital and will head to the hospital reception to meet them. Upon receipt, details of the driver, the person receiving the organ and the time the organ is received are recorded on a dedicated transplant form.

The organ is taken directly to theatres where the recipient will have been prepared for the transplant surgery. When the transport box containing the organ is opened, the TC and theatre nurse review the paper work which travelled with the organ and cross matching tissue and ensure that the donor details correlate with the expected donor details recorded in EOS. Two person checks are also undertaken on the donor's blood group between EOS and the donor blood group form that arrives with the organ. At this point the surgeon is asked to confirm that the conditions of preservation of the organ have been maintained during transport, that they have reviewed the characterisation information needed to make a decision about the organ's suitability and that they are ready to proceed with implantation.

During the transplant surgery, the perfusionist maintains a record of all perfusion fluids used during surgery. Other fluids used are recorded by theatre staff. The establishment has identified a risk that if one form was used by both the perfusionist and theatre staff then it could be that both may require it at the same time. In order to minimise the risk of this occurring the establishment uses two separate forms so that perfusion and other fluids used can be recorded simultaneously in different areas of the theatre.

Following the implantation surgery the TC returns the HTA-B form completed by the surgeon and details of the fluids used during surgery to NHSBT via secure email.

Staff at the establishment are in the process of undergoing training in the use of a normothermic perfusion device which may be used to decrease the effect of long cold ischaemic times. Staff must undergo training by the equipment manufacturer and then undertake three retrievals using the equipment while being observed by an experienced user. If assessed by the observer as competent, the surgical team will then be signed off as capable of using the equipment independently. In the future, this equipment may be used to undertake retrievals from donors following circulatory death, however, starting such activity will require the approval of NHSBT. Advice has also been given to the establishment regarding starting new retrieval programs (see advice item 7).

Deceased Organ Retrieval

The establishment's NORS team is on call every other week, with the other weeks covered by NORS teams linked to other HTA licensed establishments. The establishment uses the NHSBT's transport provider under NHSBT's contract for the provision of transport services and does not hold its own contract. The establishment's NORS team consists of two surgeons, a scrub team and a retrieval practitioner.

The TC receives a phone call from NHSBT's duty office alerting the establishment's NORS team to a potential retrieval. If the retrieval is within Scotland, the retrieval team will send a 'scout' to the donor hospital ahead of the retrieval team who may undertake additional characterisation assessments of the donor. Results from additional donor characterisation assessments are given to the SNOD who enters them onto NHSBT's systems so that they are available for review by the implanting surgeon via EOS. When mobilised, the NORS team discuss some details of the retrieval and donor during transport to the donor hospital. Upon arrival at the hospital, all NORS teams attending the retrieval undertake a full brief, which includes staff from the donor hospital and the SNOD. During the brief, the type of retrieval is discussed and plans made for the retrieval activity. Following the brief, the establishment's lead NORS surgeon reviews the consent documentation and donor's clinical notes with the SNOD and signs an NHSBT electronic document to indicate that this review has taken place.

While retrieving the organs the surgeon may speak directly to the implanting surgeon to discuss details of the organ once it has been visualised. Following the retrieval, organs are packed by the surgeon who is assisted by the scrub nurse and are placed into the transport boxes by the SNOD who also labels the boxes with the required details and passes the transport boxes to the transport driver. Prior to closure of the transport boxes the lead NORS surgeon completes the organ specific paperwork and verifies that the appropriate paperwork has been added to the transport box.

Compliance with HTA assessment criteria

All applicable HTA assessment criteria have been assessed as fully met.

Advice

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

No.	Assessment Criterion	Advice
1.	CT4	The establishment has adopted NOP006 into its Policy 12 which includes details of how the establishment maintains records relating to transplantation for the required 30 year period. The establishment has implemented a system of adding stickers to the front of the donor packs which are then annotated to include 'Records must be kept until' notice. The establishment is advised to include details of the use of these stickers within its Policy 12. In addition, the establishment is advised to amend appendix 16 of the overarching transplant manual to include all documents that are maintained within the donor packs so that appendix 16 mirrors the document list held within Policy 12.
2.	R2	The establishment has been operating as part of the NORS retrieval service for just over twelve months and the retrieval procedures have become embedded within the establishment's procedures. The establishment is advised to document the retrieval procedures, such as details of who attends retrievals, preparation of retrieval kits and use of checklists so that these procedures can become part of the establishment's existing governance framework.
3.	I1	The establishment is advised to amend the 'Verification of Donor Identity' form so that in addition to recording that the implanting surgeon is satisfied that the appropriate preservation conditions had been maintained throughout transport, and that the organ is suitable for transplant, it also is used to record that the implanting surgeon has reviewed the necessary donor and organ characterisation information. The establishment may wish to consider using the same box that relates to transport condition verification to record confirmation that the surgeon has reviewed the appropriate information and is satisfied that the organ is suitable. Recording this check will mirror the activities which Policy 8 details that the implanting surgeon undertakes prior to retrieval.
4.	I2	During the audit of clinical notes and review of the associated donor files a 'verification of donor identity' form was seen that had not been fully completed as the box to signify that the surgeon was satisfied that the appropriate preservation conditions had been maintained throughout transport of the organ had been maintained. The establishment is advised to remind staff involved in transplant surgery to ensure that all necessary forms are fully completed.
5.	S1	The establishment maintains a copy of the HTA SAEARs reporting guidance within its procedural documents however, during the audit a previous version to the current guidance was seen. The establishment is advised to download and include the most up to date version of this guidance within its documented procedural documents; a link to this document has been included below for information:- https://www.hta.gov.uk/sites/default/files/Guidance%20for%20reporting%20SAEARs%20for%20organs%20intended%20for%20transplantation%20FINAL.pdf
6.	S3	The establishment works closely with all of the laboratories which undertake donor and organ characterisation tests such as tissue typing and

No.	Assessment Criterion	Advice
		histopathology. The HTA team was informed that the laboratories would notify the establishment of any adverse events relating to testing, should they occur. The establishment is advised to confirm in writing with the leads in the relevant laboratories that the establishment must be notified of any adverse events relating to samples from the transplant unit. The establishment may wish to consider writing to the laboratory leads on a regular basis such as annually or biannually so that they are reminded of the need to report any such incidents as soon as they occur.
7.	General	The establishment is advised to inform the HTA should it commence any new transplant activity in the future such as undertaking heart transplants using donor organs from donors following circulatory death.

Concluding comments

Areas of good practice were also observed during the audit, some of which are details below.

- The establishment has developed many bespoke procedural documents which have all been incorporated into a governance and quality management system to ensure that procedures are reviewed periodically and are updated as required.

- Following the previous HTA audit the establishment has implemented a system whereby a dedicated clinical governance lead oversees SAEARs reporting to NHSBT and monitors each case to ensure that any follow up information requested is provided and that any outcomes from the investigation into the incident are acted upon.

- The NORS team holds regular multidisciplinary team meetings (MDTs) which include staff who attend organ retrievals. This provides the establishment an opportunity to review practice, identify any areas for improvement and share learning between the whole team.

The HTA has given advice to the establishment with respect to some procedural documents, checklists and communication with third party laboratories with respect to incident reporting.

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

Report sent for factual accuracy: 11 April 2017

Report returned with comments: No comments received

Final report issued: 18 May 2017

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.