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

9 May 2013

Summary of Audit findings

Golden Jubilee National Hospital (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 licenses 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 Scottish National Advanced Heart Failure Unit at Golden Jubilee National Hospital (the establishment) carries out heart transplants on adult patients. The corporate licence holder for the HTA licence is the NHS National Waiting Times Centre Board, which is an NHS Special Health Board in Scotland.

The establishment provides cardiothoracic retrieval surgeons to the multi-organ Scottish Organ Retrieval Team (SORT) based in Edinburgh. Each year consultant cardiothoracic surgeons and specialist doctors for organ retrieval attend around 30 retrievals throughout

Scotland. The establishment is taking part in the cardiothoracic 'scout' project where specialist doctors for organ retrieval are sent to donor hospitals ahead of the SORT team to enable the early assessment of DBD (donation after brain death) donors and optimise the care of donors prior to retrieval.

Tissue typing and cross matching services are provided by the Histocompatibility and Immunogenetics Laboratory at Gartnavel General Hospital.Transportation of organs for implantation at the establishment is undertaken by NHSBT commissioned transport providers.

The HTA audited Golden Jubilee National Hospital on 9 May 2013. The audit included round table discussions with key staff who work under the licence and a review of documents and records, including policy documents, patient clinical records, training records and other documentation relating to licensable activities. The establishment has amended its transplantation protocol documentation to ensure it aligns with the National Operating Procedures (NOPs) and, where appropriate, has adapted NOPs including the operating procedure which details how to report serious adverse events and reactions to NHSBT.

Compliance with HTA assessment criteria

Assessment Criteria	Audit findings	Level of Shortfall
Donor Characterisation and Organ Characterisation		
CT1) Where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from the relatives or other persons about the donor, and has explained the importance of swift transmission of information.	This criterion is not applicable. The establishment is not responsible for characterising deceased donors or organs. This activity is 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 not applicable. This activity, which applies to deceased donors, is carried out by the specialist nurse – organ donation (SN-OD) under NHSBT's licence.	**N/A**

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 adapted NOP001, which defines the donor characterisation specified in part B of the Annex to the Directive, and issued a policy document (Policy SNAHFS #001). The implanting surgeon may on occasion, request additional organ characterisation tests once the organ has been received at the hospital. The tests could include histopathological examination of biopsies. These tests are arranged by the establishment.	**None**
CT4) All information relating to donor and organ characterisation is kept for a period of 30 years from the date of retrieval of the organ and there is an operating procedure in place to demonstrate how this requirement is complied with.	This criterion is fully met. The establishment has a policy on the management of medical records, which includes a records retention schedule (GJNH Guidelines for the Management of Health Records). This policy is guided by Scottish legislation. The schedule requires transplant records, including patient records, records of investigations and storage of specimens relating to transplantation, to be retained for 30 years. See assessement under criterion TC3.	**None**
CT5) Tests required for donor and organ characterisation are carried out by laboratories with CPA accreditation.	This criterion is fully met. Tissue typing and cross matching services are provided by the Histocompatibility and Immunogenetics Laboratory at Gartnavel General Hospital. This laboratory has Clinical Pathology Accreditation (CPA) and European Federation of Immunogentics (EFI) accreditation. The certificates were reviewed during the audit. NHSBT is responsible for ensuring that the required tests for deceased donor and organ characterisation are carried out. This is arranged by the SN-ODs.	**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.	The on-call transplant coordinator (TC) receives a provisional or full offer of a donor heart from either the SN-OD or NHSBT Duty office along with the Electronic Offering System (EOS) number. Fast-Fax offers are received by the hospital switchboard and immediately conveyed to the TC. The TC logs onto EOS and completes a "GJNH donor referral form" which is used to record information required by Part A and B of the Annex to the Directive and information required by the implanting cardiothoracic surgeon. If the donor is from Europe, the TC records the import number provided by NHSBT Duty office. The date and time of the offer and conversations between the TC and the on-call implanting surgeon, SN-OD and NHSBT Duty office are also documented on the form.	**None**
	The retrieving surgeon informs the implanting cardiac surgeon as soon as the donor cross clamp is applied. The retrieving surgeon is also responsible for notifying the TC and implanting surgeon immediately if the retrieved heart/lungs appears sub-optimal or if any damage occurs to the organs during retrieval, or if there are other factors which may affect the success of the transplant. The establishment has adapted the contents of NOP001 and NOP002, which define donor and organ characterisation and transmission of information to the implanting surgeon, in local policy documents (Policy SNAHFS #001 and #002).	

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 establishment has adapted the contents of NOP002 in a policy document (Policy SNAHFS #002), which covers this requirement. The following checks are performed before the start of any retrieval: • The retrieving surgeon verifies that authorisation is in place for donation of organs for transplantation and this is recorded on the Surgical Safety checklist. • Where appropriate, the retrieving surgeon also checks that the Procurator Fiscal has been informed and has given consent for the donation to proceed. This consent is recorded on the Authorisation Form.	**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. Most of the equipment used by the SORT team during retrieval is provided by another HTA licensed establishment. Any equipment taken by surgeons based at Golden Jubilee hospital for use at the donor hospital is covered by the following documented procedures - (i) Management of procurement material and equipment in deceased donation and transplantation (CT-NS-HTS-POL-10); (ii) Organ Transplant Supplementary Procurement Policy (QPMAT016B); (iii) GJNH Tendering and Contracting Document QPMA1 016. The establishment has adapted the contents of NOP004 in a policy document (Policy SNAHFS #004), which covers this regulatory requirement.	**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 fuly met. The establishment has adapted the contents of NOP004 in a policy document (Policy SNAHFS #004) which covers this requirement. If required, the retrieval surgeon performs a transoesophagaeal echo (TOE) test on the donor. The surgeon takes the TOE probe to the donor hospital. The probe is decontaminated at the donor hospital after use, in accordance with the procedure - Decontamination and Preparation of TOE Probe used by the Cardiothoracic Retrieval Team (CT-NS-HTS-PRT-20,) before it is brought back to the establishment. All other reusable instruments used by the SORT team are returned to another licensed establishment for sterilisation. *The HTA has given advice against this criterion (see Advice 1 below).*	**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 not applicable The establishment does not transplant organs from living donors.	**N/A**

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. See assessment under criterion 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. Reusable instruments are decontaminated at the Central Sterile Processing Department (CSPD) located on the hospital site. The revalidation reports for the CSPD were reviewed during the audit. The establishment has adapted the contents of NOP004 in a policy document (Policy SNAHFS #004) which covers this requirement.	**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. Staff record details of perfusion fluids (type, manufacture and batch number) used during retrieval in the HTA A form. Details of perfusion fluids used after the heart is received in theatre is recorded in the "GJNH Perfusion and Preservation Fluid Record" form. Completed forms were reviewed during the audit.	**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 adapted the contents of NOP003 in a policy document (Policy SNAHFS #003) containing additional details on packing of organs and instructions on how to correctly label the transport box – "Packaging, Labelling and Transport of Organs in Deceased Donation and Transplantation" (CT-NS-HTA-POL-9). The TC is responsible for organising transport of organs from donor hospitals to the establishment using local NHSBT commissioned transport providers. The TC monitors the transport of the organ en-route to the establishment, as cold ischaemia times have a critical impact on cardiac transplant outcomes. Staff complete the "GJNH transport record" when the organ arrives at the establishment. The form is used to record the time of arrival of the organ, name of delivery personnel, the donor hospital, a check of the security tag number and the integrity of the organ box.	**None**

TP2) The organ shipping container is suitable for transport of the specified organ.	This criterion is fully met. The SORT team uses proprietary cool boxes to transport hearts and lungs. The establishment will use validated transport boxes when they are issued by 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. See assessment of criterion TP1 above. It is the retrieval surgeon's responsibility to ensure that the organ box is labelled correctly.	**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 adapted the contents of NOP003 in a policy document (Policy SNAHFS #003), which details what information must accompany the organ during transportation. All transported organs are accompanied by the HTA A form (Cardiothoracic Donor information form), which is signed by the retrieval surgeon. The SN-OD also uploads information on donor characterisation onto EOS.	**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 does not hold a contract for the transportation of organs, but relies on NHSBT's contractual agreements with transport companies. Transport requirements are detailed in "NHSBT Specification for the Provision of Transport for Human Organs". When the establishment's retrieval surgeon is accompanying retrieved organs back to the establishment for implantation, the retrieval surgeon is responsible for reporting any serious adverse events which occur en route.	**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 adapted the contents of NOP002 in a policy document (Policy SNAHFS #002), which details the checks which have to be carried out by the implanting surgeon. These checks include donor identity, the HTA A form (Cardiothoracic Donor information form), donor blood group forms and the tissue sample label and are documented in the "GJNH verification form". The implanting surgeon also reviews the "GJNH donor referral form" completed by the TC and the information on EOS before implantation.	**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 slush ice levels are checked by the surgeon when the transport box is delivered to the theatre. Confirmation of appropriate transport conditions and packaging of the heart is documented in the "GJNH verification 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. The establishment's Cardiac Transplantation Protocol states that a risk/benefit analysis is undertaken by the implanting surgeon if any of the information required to characterise the donor, including information specified in Anex A of the Directive, is not available. The risk/benefit analysis is documented in the recipient's clinical notes prior to implantation.	**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 adapted the contents of NOP006 in local documentation (Policy SNAHFS #006). The establishment's Cardiac Transplantation Protocol includes a procedure - "Management of data to ensure traceability" - which details the return of the HTA A (Cardiothoracic Donor information form) or HTA B forms along with "GJNH perfusion and preservation fluid records" to NHSBT within seven days. *The HTA has given advice against this criterion (see Advice 2 below).*	**None**
TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.	This criterion is fully met. Each deceased donor is assigned a unique NHSBT ODT number, which is recorded on EOS and on the HTA A form. Recipients are identified by their name, NHS number, where appropriate their Community Health Index Number(CHI number), and date of birth.	**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. Staff record the time of arrival of the heart in the "GJNH transport record". The establishment's Cardiac Transplantation Protocol includes a documented procedure – Management of data to ensure traceability – which states that transport records are retained for 30 years. The NHS retention schedule for medical records, which is included in GJNH Guidelines for the Management of Health Records, requires transplant records, including patient records and records of investigations and storage of specimens relating to transplantation, to be retained for 30 years. However, the schedule states that other records relating to transplant should only be retained for three years. *The HTA has given advice against this criterion (see Advice 3 below).*	**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 fully adopted NHSBT Standard Operating Procedure SOP3888/1 Reporting an Organ Donation or Transplantation Incident to NHSBT, and staff are aware of the reporting requirement. The establishment has an incident reporting policy and procedure. Organ transplant incidents are discussed at the regular multidisciplinary team meetings and at clinical governace meetings.	**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. See assessment under criterion S1. *The HTA has given advice against this criterion (see Advice 4 below).*	**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. Transport is undertaken by NHSBT commissioned transport providers who are aware of the requirement to report incidents relating to transportation. The Histocompatibility and Immunogenetics Laboratory at Gartnavel General Hospital is aware that issues relating to deceased donor samples must be reported to NHSBT as a serious adverse event.	**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. During the audit, surgical staff appraisals, log books and forms used to assess organ retrieval competencies were reviewed.	**None**

GN2) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are provided with the training necessary to perform their tasks.	This criterion is fully met. New theatre staff are provided with the "Cardiac theatre orientation pack" and training as required. Theatre staff CPD records were also reviewed.	**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 adapted the contents of NOP005 in a policy document (Policy SNAHFS #005), which details the medical activities performed under the guidance of a registered medical practitioner.	**None**

Advice

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

No.	Assessment Criterion	Advice
1.	R3	The HTA advises the establishment to update the procedure - Decontamination and Preparation of TOE Probe used by the Cardiothoracic Retrieval Team (CT-NS-HTS-PRT-20) in order to reflect current practice. The TOE probe is decontaminated at the donor hospital prior to the return of the retrieval team; it is not brought back to the establishment for decontamination as stated in the procedure.
2.	TC1	The HTA advises the establishment to consider setting up a system to monitor the return of HTA B forms in order to ensure that they are returned to NHSBT within seven days.
3.	TC3	The HTA advises the establishment to amend the GJNH "Guidelines for the Management of Health Records" to clarify the retention schedule for records relating to transplantation which are not part of patient records, investigations or storage of specimens relating to transplantation in order to ensure that transport and other traceability records are retained for 30 years. This will help to ensure that the records management department within the establishment is aware of this legal requirement. The HTA notes that the 30 year retention requirement is stated in the procedure – Management of data to ensure traceability – which is within the Heart Failure Service Cardiac Transplantation Protocol.
4.	S2	The HTA advises the establishment to nominate a key member of staff who will be responsible for reporting serious adverse events and reactions to NHSBT. This will help to clarify the lines of responsibilities for reporting such incidents to NHSBT.

Concluding comments

The surgeons, clinicians, transplant coordinators, perfusion and theatre staff work well

together as a team. There were several examples of good practice.

Staff at the establishment worked as a team to update the Unit's Cardiac Transplant Protocol to include documented procedures which comply with the regulatory requirements. This overarching document provides clinical guidance and incorporates the adapted National Operating procedures and all forms used by the Heart Failure unit when undertaking licensable activities.

The establishment has good systems in place for record keeping. Working practices are effective and there is excellent communication between staff.

The HTA has given advice to the establishment in relation to updating and amending two documents, nominating a key member of staff who is responsible for reporting serious adverse events and reactions to NHSBT and setting up a system to monitor the return of HTA B forms to NHSBT.

The audit team was impressed with the dedication and professionalism of staff who work under the extremely tight timeframes required for successful cardiothoracic retrieval and implantation. The audit team would like to thank them for explaining their working practices and for their courtesy during the audit.

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

Report sent for factual accuracy: 13 June 2013

Report returned with comments: 1 July 2013

Final report issued: 2nd 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.