Audit report on compliance with licensing assessment criteria
Audit dates: 6 and 9 - 10 June 2022

NHS Blood and Transplant

HTA licensing number 40056

Licensed under the Human Tissue Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

Licensed activities – Procurement

Organ type	Heart	Lung	Liver	Kidney	Small Bowel	Pancreas
Adult deceased	**DC, OC, T**	**DC, OC, T**	**DC, OC, T, P**	**DC, OC, T, P**	**DC, OC, T**	**DC, OC, T, P**
Paediatric deceased	**DC, OC, T**	**DC, OC, T**	**DC, OC, T, P**	**DC, OC, T, P**	**DC, OC, T**	**DC, OC, T, P**

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)

Summary of audit findings

NHS Blood & Transplant (NHSBT) (the establishment) was found to have met all HTA assessment criteria that were assessed as part of the audit.

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

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 practice:

Number	Assessment Criterion	Advice
1.	CT2	Although staff that were interviewed know the procedure to follow, the recording of verbal results and the witnessing of them is not documented. The establishment is advised to incorporate the procedure relating to the verbal receipt of laboratory test results so that this process is fully documented within the establishment's standard operating procedures. In addition, section 8.2 of the procedure has a typographical error relating to microbiological blood reports which may lead to confusion. The establishment is advised to correct the wording.
2.	CT5	The establishment is advised to review the contract with the testing laboratories and consider what updates, other than those already included, it may like to receive from them. For example, the establishment may wish to be made aware if a laboratory were to change the type of assay performed for a particular test or make changes to a testing platform. If this is something that the establishment determines it would like to be made aware of, the establishment is advised to update the agreements with the newly commissioned laboratories to include these areas.

Background

NHSBT is a Special Health Authority with responsibilities for organ donation and transplantation across the United Kingdom. The establishment is responsible for donor consent, donor characterisation and transport of donor organs between retrieval and implantation hospitals.

The establishment has been licensed by the HTA since September 2012. This was the establishment's third audit with the most recent previous audit taking place in March 2017.

Since the audit in 2017, there have been some changes to the activities undertaken under the licence and changes to the operating environment in which these activities take place. These are highlighted and summarised below.

There has been legislative change in England and Scotland regarding deceased organ and tissue donation consent/authorisation. The change allows donor consent/authorisation to be deemed for the purpose of transplantation in certain circumstances. These changes were discussed with the establishment during the audit in addition to the training that has been, and continues to be, rolled out to establishment staff. Finally, an upcoming change to the consent legislation in Northern Ireland was discussed with establishment staff including how training will be disseminated.

Since April 2022, the establishment commissions the laboratories that undertake donor serological testing and tissue typing analysis. These changes were discussed during the audit with regards to services being commissioned, laboratory (United Kingdom Accreditation Service (UKAS) accreditation status monitoring, the contractual arrangements in place with the laboratories and the review of these arrangements. Also discussed was an on-going project which means that donor characterisation serology testing results from the commissioned laboratories will be transferred directly to the establishment's database without the need for manual data entry. The direct transfer of laboratory data will commence later in 2022 and be rolled out gradually as part of a managed programme until all commissioned laboratories transfer results in this way.

The establishment has changed its transport provider since the previous audit. Discussions were held with the establishment regarding the monitoring of the new service and if procedures regarding transportation have changed. The establishment and transport company

have regular meetings and contact points to discuss the service and any issues that may have arisen. In addition, other services, such as the national organ retrieval service (NORS), have an opportunity to discuss the new service and feed back to the establishment at regular meetings. On-going monitoring of the contract was discussed with the establishment including the frequency and mechanisms through which this is undertaken.

The HTA audit team also held discussions regarding newly implemented and planned additional donor characterisation testing, such as tests for HHV8. Discussions were also undertaken with regards to reviewing emerging diseases and additional testing.

Description of activities undertaken

The following areas were covered during the audit:

Criteria assessed against during the audit
Assessment criteria R1 to R4, P1 to P3, I1 to I3, TC1 and TC3, were not reviewed as part of this audit as these standards do not apply to the establishment. The remaining assessment criteria were reviewed during the audit.

Review of governance documentation
Documentation regarding the commissioning of the laboratories, staff training and donor and organ characterisation procedures were reviewed.

Visual inspection
The HTA audit team visited establishment sites in Bristol and Liverpool. Discussions were held with establishment staff regarding donor testing, donor characterisation, transport company arrangements, consent training and incidents.

Audit of records
The establishment provided the audit team with donor identifiers relating to donors from different areas of the country. At the Bristol premises, records relating to each donor were reviewed within the establishment's transplant database. At both sites, records relating to

donor and organ characterisation were reviewed and discussed with Specialist Nurses for Organ Donation (SNODs) or Specialist Requestors by reviewing the data held within the establishment's 'donorpath' portal. Each donor from a specific region was discussed with a SNOD from the same region. Finally, at Liverpool during the visit to the donor family care service (DFCS), the collated donor information files including hard copies of blood groups and testing results, in addition to information gathered from the donor's GP, were also reviewed. Details of an additional donor that did not proceed to donation were also reviewed at the DFCS.

Report sent for factual accuracy: 11 July 2022

Report returned with comments: 27 July 2022

Final report issued: 3 August 2022

Appendix 1: 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 (as amended) 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 2: 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.

Appendix 2: 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 the 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 (as amended)** 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 the final audit report. The establishment 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 site-visit audit
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site-visit audit

After an assessment of the proposed action plan, the establishment will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA Assessment criteria

The HTA assessment criteria applicable to this establishment are shown below; those not assessed during the audit are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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 endeavored 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).
CT2) Donors and organs are characterised before implantation by the collection of information specified in Annex A of The Quality and Safety of Organs Intended for Transplantation: A documentary framework.
CT3) Donors and organs are characterised before implantation by, where considered appropriate, the collection of information specified in Annex B of The Quality and Safety of Organs Intended for Transplantation: A documentary framework.
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.
CT5) Tests required for donor and organ characterisation are carried out by laboratories with United Kingdom Accreditation Service (UKAS) accreditation (to ISO15189:2021).
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.

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.
R2) Material and equipment used in retrieval meets the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.

R3) Reusable instruments used in retrieval are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
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

Organ preservation

P1) Material and equipment used in organ preservation meet the requirements of The Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.
P2) Reusable instruments used in organ preservation are subject to a validated cleaning and sterilisation procedure for removal of infectious agents, which is documented.
P3) Records of perfusion fluid coming into contact with organs are made on the appropriate HTA A and B forms.

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.
TP2) The organ shipping container is suitable for transport of the specified organ.
TP3) The organ shipping container used for transporting organs from the licensed premises is labelled with the information specified in The Quality and Safety of Organs Intended for Transplantation: A documentary framework, and there is an operating procedure in place to

demonstrate how this requirement is complied with.
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.
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.

Implantation

I1) The identification of the donor and the collection of the information in Annex A and B of The Quality and Safety of Organs Intended for transplantation: A documentary framework, are verified prior proceeding to implant an organ, and there is an operating procedure in place to demonstrate how this requirement is complied with.
I2) Compliance with the conditions of preservation and transport outlined in The Quality and Safety of Organs Intended for Transplantation: A documentary framework are verified prior to proceeding to implant an organ.
I3) Where any of the information specified in Annex A of The Quality and Safety of Organs Intended for Transplantation: A documentary framework 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.

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.

TC2) There is an identification system for donor and recipient to identify each donation and each of the organs and recipients associated with it.
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.

Serious adverse events and adverse 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.
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.
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.

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.
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.

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.