Audit report on compliance with licensing assessment criteria
Date: 18-19 February 2025

Belfast Health and Social Care Trust

HTA licensing number 40046

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

Licensed activities – Procurement

Organ type	Kidney
Adult (living donor)	**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)

Licensed activities – Transplant

Organ type	Kidney
Adult recipient	**OC, P, T & I**
Paediatric recipient	**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)

Summary of audit findings

Although the HTA found that Belfast Health and Social Care Trust (the establishment) had met the majority of the HTA's assessment criteria that were assessed as part of the audit, one major and one minor shortfall were found against assessment criteria for Organ preservation and Serious adverse events and reactions (SAEARs).

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.

Compliance with HTA assessment criteria

Major shortfalls

Assessment criteria	Audit findings	Level of shortfall
Serious adverse events and adverse reactions (SAEARs) – (these criteria apply to all licensed activities)		
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.	A review of incidents recorded within the establishment's internal incident system was undertaken. Three of the incidents that were reviewed were found to have met the criteria of a SAEAR however these incidents had not been reported to NHSBT as required. The establishment is advised to liaise with NHSBT to determine if the incidents identified should be retrospectively reported as SAEARs. *This shortfall was identified at the previous inspection in 2022.*	**Major**

Minor Shortfalls

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) (as amended) (UK MDR 2002), where these apply, and there is an operating procedure in place to demonstrate how this requirement is complied with.	To meet the requirements of the Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002), manufacturers must stipulate the storage conditions for material and equipment used in organ preservation. The perfusion fluid used by the establishment was introduced in December 2024 and should be maintained at 2-6°C. This temperature range is different to the perfusion fluid used previously. The establishment stores a working stock of perfusion fluid in a fridge located in theatres at both Belfast City Hospital and Belfast Children's Hospital. The establishment have not changed the higher alarm trigger point of the fridges to reflect the new perfusion fluid temperature range at either site. A review of the recorded temperature readings indicated that the fridge regularly reached close to the higher recommended storage temperature of the current perfusion fluids. *See advice Item 2.*	**Minor**

The HTA requires the establishment to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 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.

Advice

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

Number	Assessment Criterion	Advice
1.	R4	Upon discharge of a living donor, a letter is sent to the donor's GP and a further letter sent at the donor's annual check up. The establishment include a reminder in the annual letter that should the living donor present with any medical conditions which may have an impact for the organ recipient, the establishment is informed so that the recipient can be followed up as necessary. The establishment is advised to include this reminder in the initial letter as well, as this may facilitate earlier detection of medical conditions that could impact an organ recipient especially if the donor is from overseas.
2.	P1	The fridge temperature at Belfast City Hospital is monitored using a minimum/maximum thermometer and the temperature readings are recorded in a logbook. A review of the recorded temperatures indicated that there had been regular temperature excursions with no evidence that these were addressed. The establishment is advised to ensure staff are aware of the procedure if any temperature excursions occur. Belfast Children's Hospital do not record the minimum/maximum temperature of the fridge in which perfusion fluid is stored. The establishment would be unaware of a temperature excursion which may affect the viability of the perfusion fluid. The establishment are advised to use a minimum-maximum calibrated thermometer, so they are aware if any temperature excursions occur. The establishment is advised to look at alternative arrangements for the storage of the spleen and lymph nodes as the current storage fridge also stores medication and space is limited.

Number	Assessment Criterion	Advice
3.	TC3	On arrival of the kidney at Belfast City Hospital a receipt book is completed which includes a secondary copy. The secondary copy is kept in the event of the loss of the original form. When reviewing the book, not all copies of the kidney transport form were legible through the carbon copy. The establishment is advised to ensure that copy is legible for traceability purposes.
4.	TP1	A number of kidneys can be stored in the room on the ward at Belfast City Hospital ready for transplant. If the kidney is not transplanted it is returned to the storage area on the ward. There is no specific area for the returned kidney to be stored. The establishment is advised to have a separate storage area and labelling system for kidneys which cannot be transplanted.
5.	I1	During the audit of transplant records, a number of examples were found where paperwork had not been completed as per procedure or had been incorrectly recorded. For example, for one living donor the HTA B form had the incorrect perfusion fluid type and expiry date. Operation notes for one case had not been signed by the scrub nurse or surgeon. For one living donor, the date of decision of HTA for approval was not recorded. The establishment is advised to consider undertaking periodic audits to help give assurance that transplant records are fully completed.
6.	S1	Although there is an establishment procedure in place for reporting incidents, the establishment is advised to look at the flow of reporting incidents to ensure reporting to NHSBT within 24hrs of discovery. The establishment is also advised to formalise the process of having representatives follow up with NHSBT.
7.	GN2	The establishment records the training of transplant coordinators as they gain competency in their

Number	Assessment Criterion	Advice
		role. The establishment is advised to consider adding the procedural document references into the competency sign off records so that the documented procedures against which the coordinators have been trained are recorded.

Background

The establishment has been licensed by the HTA since December 2012. This was the establishment's fourth audit. The most recent previous audit took place in March 2022. Since then, there has been significant changes to staffing in the team.

Description of audit activities undertaken

Criteria assessed against during the audit
Of the 30 assessment criteria, 29 of these were assessed during the audit. Assessment criteria CT1 was not assessed as the establishment is not responsible for characterisation of deceased donors.

Review of governance documentation
The following documents were reviewed: Establishment's policies and procedures, accreditation certificates for the Histocompatibility and Immunogenetics (H&I) and Microbiology and Pathology laboratories. The audit team also reviewed certification of the sterile services provider, records retention policy and a live donor questionnaire.

Visual inspection
A visit to the room within the establishment's theatre suite where organs are received and where perfusion fluids and specimens are kept, was undertaken. Discussions about monitoring the storage temperature of perfusion fluids and specimens were held with staff.

Audit of records
The following transplant records were reviewed:

- One set of records from a donor following death by neurological criteria (DBD) and two sets of records from donors whose death had been confirmed using circulatory criteria (DCD)
- Five sets of records for a directed donation for a living kidney transplant
- Two sets of records for paired / pooled kidney donation

The inspection team reviewed transplant coordinator notes, transport records and records of receipt of organs, operation notes, records of perfusion fluids used, HTA A and HTA B forms, cross match results, and serology tests.

Report sent for factual accuracy: 11 March 2025

Report returned with comments: No comments received.

Final report issued: 8 April 2025

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.