

## Audit report on compliance with licensing assessment criteria

Date: 18 March 2026



### North Bristol NHS Trust HTA licensing number 40048

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)	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)

#### Licensed activities – Transplant

Organ type	Kidney
Adult living	OC, P, T, I
Adult deceased	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 North Bristol NHS Trust (the establishment) had met the majority of the HTA's assessment criteria that were assessed as part of the audit, two major shortfalls were found against assessment criteria for Donor Characterisation and Organ Characterisation, Retrieval of Organs for transplantation and Organ preservation.

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
<b>Donor Characterisation and Organ Characterisation</b>		
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.	During a review of living donor characterisation records an example was found where, based on the donor's travel and medical history, SaBTO microbiological safety guidelines advise that follow up tests should have been undertaken. However, the audit team found no documented evidence that any relevant additional tests had been carried out.	Major
<b>Retrieval of Organs for transplantation</b>		
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.	During a review of temperature monitoring records, considerable inconsistencies in the completion of the temperature monitoring form were found. This was in relation to the fridge where perfusion fluid is stored. The inconsistencies dated back to early 2025. There is no temperature monitoring in place for perfusion fluid used for the normothermic perfusion machine. The establishment has a process in place whereby pharmacy and renal ward staff undertake an audit of the temperature monitoring forms. There is no evidence that this process has been followed.  <i>See advice item 2.</i>	Major

<b>Organ preservation</b>	
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.	

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:

<b>Number</b>	<b>Assessment Criterion</b>	<b>Advice</b>
1.	CT(4)	During the traceability audit of records, the inspection team could not review the Medical and Social History (MASH) document for one case. For traceability purposes, the establishment is advised to ensure that staff can access obsolete electronic systems.
2.	R(2) P(1)	The establishment is advised to record the maximum and minimum temperature where perfusion fluid is stored so that they can be assured that the storage temperature remains within appropriate

Number	Assessment Criterion	Advice
		<p>parameters between measurements.</p> <p>The establishment is advised to lower the upper alarm limit of the fridge storing perfusion fluid to under 8°C. This may help to ensure that staff have time to investigate if there is a temperature excursion.</p>
3.	TP(1)	<p>The establishment is advised to include the following in the standard operating procedure (SOP) on arrival of the kidney onto the renal ward:</p> <ul style="list-style-type: none"> <li>• calling porters to collect spleen and lymph nodes;</li> <li>• an additional section on the kidney arrival checklist. This may help to document if the kidney is transported to another transplant centre or disposed of; and</li> <li>• to include the process for storing the kidneys boxes on individual trolleys in the procedure room.</li> </ul> <p>A diary is used to record when the spleen and lymph nodes are collected to be transported to the laboratory for crossmatch testing. The inspection team noted that several stickers were not fully completed. The establishment is advised to include an audit of the diary to ensure that the stickers are fully completed for traceability purposes.</p>
4.	General	<p>Staff have been trained by the manufacturer to use the normothermic perfusion machine. This training has been disseminated to theatre staff. The establishment is advised that staff document in their training records when this training has taken place.</p>

## **Background**

The establishment has been licensed by the HTA since December 2012. This was the establishment's fourth site visit. The most recent previous audit took place in January 2023.

Since the audit in 2023, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

## **Description of audit activities undertaken**

### *Criteria assessed against during the audit*

The establishment was assessed against 29 of the 30 applicable criteria. Criteria CT1 was not applicable as the establishment is not responsible for obtaining information relating to a deceased donor.

### *Review of governance documentation*

Procedural documents relating to licensed activities and accreditation certificates for the following laboratories:

Histocompatibility and Immunogenetics (H&I)

Histopathology

Pathology.

The procurement policy demonstrating how the Medical Devices Regulations 2002 (SI 2002/618) (as amended) (UK MDR 2002) requirement is complied with, and certification of the sterile services provider were also reviewed.

In addition, a selection of incidents were reviewed and discussed with establishment staff.

### *Visual inspection*

A visit to the room within the establishment where organs are received and perfusion fluids are kept was undertaken. Discussions about monitoring the storage temperature of perfusion fluids were held with staff.

### *Audit of records*

Records relating to three living kidney donor transplants were reviewed. Donor questionnaire, hard copy blood group forms, cross match results, multidisciplinary team (MDT) and surgical suitability sign off records, HTA approval, HTA A and HTA B forms and donor and recipient consent records were reviewed. One case found that additional serology tests had not been carried out.

Records relating to two deceased donor kidney transplants were reviewed. Transplant coordinator notes, MASH forms for one case; HTA A and HTA B forms, operation notes, donor blood group hard copy forms, organ safety checklists, recipient consent forms and the records of organ receipt were reviewed. For one case the MASH form could not be reviewed.

**Report sent for factual accuracy: 27 March 2026**

**Report returned with comments: No comments received**

**Final report issued: 14 April 2026**

## **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
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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.