Inspection report on compliance with HTA licensing standards
Inspection date: **09 May 2024**

Great Western Hospital
HTA licensing number 12003

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site Great Western Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
A&E		*Carried out*	

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Great Western Hospital ('the establishment') had met the majority of the HTA's standards, three major and three minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.
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 inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst the SOP states who may seek consent and the training they must receive, there is no information regarding the frequency of refresher training and an assessment of competency. Additionally, the information regarding a cooling off period is unclear, and not reflective of information provided to those giving consent.	**Major**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	Mortuary and Maternity staff have not been supported to keep up to date with consent training, including the lead person who delivers internal consent training to other staff groups.	**Major (cumulative)**

b) Records demonstrate up-to-date staff training	There were no records available to review demonstrating up-to-date staff training. *(as a result, standard C2(c) cannot be assessed)*	
d) Competency is assessed and maintained	There are no documents available for review demonstrating staff competency with the HTA requirements when seeking consent for perinatal and adult hospital consented PMs.	
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The transfer form used by maternity staff transferring the deceased from the mortuary for a ward based viewing does not have three identifiers. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.* Additionally, whilst family members attending a viewing are asked to provide three identifiers, these do not match the information recorded on the body's ID bands. This poses the risk of an incident pertaining to the viewing of the wrong body.	**Major (cumulative)**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Whilst the type of tissue taken during PM is recorded. The number of samples taken is not recorded on the paper documentation or the spreadsheet held in the Mortuary or Pathology laboratory.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Whilst the Consent Policy had been reviewed by someone other than the author and was ratified and version controlled, there were two versions available for use. The inspection team were sent an outdated version of the document for review. The current version was sent to the inspection team after the onsite inspection had been carried out. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Whilst all procedures relating to licensed activities have been risk assessed, not all risks have been reviewed in line with the establishment governance framework. These include but are not limited to: - MOR-RI-008- Fridge room - MOR-RI-010- Releasing to Funeral Directors - MOR-RI-011- Transportation of organs and tissues to other hospitals This is not an exhaustive list of the risk assessments requiring review. To fully address this shortfall, the establishment should review all risk assessments relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The fridge used for the storage of toxicology samples awaiting transfer to the pathology lab is not attached to the central alarm system. Whilst the fridge does have an audible local alarm, it would not be heard out of hours. This poses the risk of damage to the tissue samples. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

The HTA requires the DI 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 DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ6(a)	The DI is advised to consider adding the category of HTARI to the Risk Assessments as this will help to support identification and reporting of incidents
2.	T2(b)	The DI is advised to liaise with HM Coroner to ask for the RSE form to be altered to support the sensitive disposal of residual tissue immediately after it has been blocked and is no longer required.
3.	T2(d)	The DI is advised to add the method of disposal of tissue to the electronic tissue spreadsheet in addition to paper records.

4.	PFE1(d)	Whilst located in a secure compound which is only accessed by hospital staff. The DI is advised to consider adding a tamper proof device to the switches of the external compressor units, this will prevent them being inadvertently switched off. Additionally, consideration should be given to the addition of a battery operated contingency to the existing door locking mechanism in the event of loss of power to the mortuary.

Background

Great Western Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place on 27 and 28 July 2021 this was a virtual inspection. The most recent previous site visit was undertaken in January 2016.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence. However, there has been a change to the named personnel on the licence with a change of Corporate License Holder contact (CLHc) in February 2023.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff.

Visual inspection
The inspection included a visual assessment of the establishment including the post mortem suite, body storage areas and viewing rooms. Areas outside the mortuary carrying out licensed activity were also visited including the Pathology department. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of three bodies in refrigerated storage and one body in long term frozen storage. The admission of one body and release of one body into the care of the Funeral Director was observed. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held electronically. No discrepancies were identified. Audits of traceability were conducted for three cases of histology samples. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, Senior APT, Quality Manager, Trainee APT, Biomedical Scientist, Porter, Porter Supervisor, Adult Pathologist and Adult Consent Seeker.

Report sent to DI for factual accuracy: 16/05/2024

Report returned from DI: 23/05/2024

Final report issued: 03/06/2024

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 2 September 2024

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard 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 expected standard, 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 Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or

- indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

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 inspection 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, but which indicates a departure from expected standards.

   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 inspection.

   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 inspection 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 inspection report. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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