Inspection report on compliance with HTA licensing standards
Inspection date: **22&23 June 2022**

Whittington Hospital
HTA licensing number 12099

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 Whittington Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	*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 Whittington Hospital ('the establishment') had met the majority of the HTA's standards, 6 major and one 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
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	There are risk assessments relating to use of the lower levels of fridge and freezer storage in the body store and post mortem room. However, controls do not mitigate identified risks. The inspection team observed a body being removed from the bottom of the freezer storage. The trolleys in use do not adjust to be used at the lowest level and as such mortuary staff must manually lift patients on trays risking accidental damage to bodies and injury to staff.	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	**Body store** The floor of some fridges cannot be cleaned thoroughly due to being constructed of metal sheeting with raised chequered patterning. These have areas covered with limescale. (See also PFE2 (d) below) The water-resistant floor covering does not reach the walls in some areas leaving exposed porous material which cannot be cleaned. There is a leak from the ceiling in a corner of the body store which allows water in when it rains. A drainage pipe from the fridge unit is leaking fluid onto the floor of the body store. **Post mortem room** Walls are damaged and have some areas of exposed plaster which is porous. Some areas of wall covering for the lower part of the walls are not sealed with gaps to bare walling behind. The flooring is damaged in areas, not sealed and uneven in areas causing water pooling following cleaning.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The facility has insufficient fridge storage to meet demand. Off-site contracted contingency measures are used regularly which requires bodies to be transferred in unrefrigerated vehicles to a contracted storage facility in Kent. Bodies are returned to the establishment for release to funeral directors at a later date. This also increases the risk of deterioration of the condition of bodies and raises the risk of accidental damage to bodies due to being moved more frequently.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is insufficient freezer storage. At the time of the inspection the six freezer units were full and there was one body that had been in storage for over 30 days that could not be placed in the freezer. There is no bariatric freezer storage and no contingency arrangements.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	The floor of fridge unit 2 is constructed of embossed patterned metal which has gaps between some sheets. This also allows drainage to the floor beneath rather into a drainage system. Due to the structure of the flooring, it cannot be thoroughly cleaned and there is a build-up of limescale in some areas (See also PFE1(a) above)	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	Some items of equipment in the PM room are constructed from wooden material, which is porous and cannot be thoroughly cleaned, this includes a lectern, wall mounted storage unit and stepover bench.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	There is no signage to indicate clean, dirty and transitional areas relating to the post mortem room.	**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.	GQ1 (b)	Whilst procedures on evisceration ensure that it is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed, the DI is advised to review the SOP to clarify areas of responsibility.
2.	GQ5 (a)	Whilst the porter manager interviewed was aware of internal incident reporting and the types of incidents to be reported, they were unaware that some incidents in which they may be involved are

		reported to the HTA. The DI is advised to include this in the training provided to both porters and maternity staff.
3.	T1 (c)	Whilst three identifiers are used to identify bodies for release. The inspection team witnessed a release where a funeral director was initially unable to provide the required unique identification to check against that recorded on labels on the body. Identity was fully confirmed prior to release. The DI is advised to review this process to enable staff to complete relevant checks on information on labels without seeking clarity from other records.
4.	PFE2 (e)	Fridge and freezer units in the mortuary 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 unit in the maternity department is also alarmed and monitored by staff. The DI is advised to add this to the formalised tested schedule conducted for the mortuary.

Background

Whittington Hospital has been licensed by the HTA since 11 July 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in December 2017.

Since the previous inspection, the establishment have stopped conducting viewings on site.

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 team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Evidence of staff training, and competency assessment were reviewed as well as the qualification certificates of mortuary staff. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, the PM room, the maternity department and the storage arrangements for relevant material held within the mortuary.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included a body in long term freezer storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and associated patient tracking files. No discrepancies with traceability were identified.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, family wishes forms, and tissue blocks, and slides being stored. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, portering staff, staff involved in the consent seeking process, a pathologist undertaking PM examination, and the DI. The inspection team also met with the quality manager and the mortuary manager.

Report sent to DI for factual accuracy: 18/07/2022

Report returned from DI: 25/07/2022

Final report issued: 26/07/2022

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: 25 September 2023

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.