Inspection report on compliance with HTA licensing standards
Inspection date: **27 September 2023**

Wexham Park Hospital
HTA licensing number 12323

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 **Wexham Park 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 Wexham Park Hospital (‘the establishment’) had met the majority of the HTA’s standards, five major and two 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.

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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	Whilst there is a documented consent policy which reflects the HT Act and HTA's codes of practice, the policy for adult consent seeking had not received a documented review since approval in 2015. There was no documented review of the perinatal consent seeking policy since approval in 2017. Additionally, the perinatal consent policy did not detail how consent was obtained prior to the removal of relevant material from the deceased for microbiological analysis.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst there was an SOP in place detailing the consent process, this was included in the consent seeking policies. The adult consent seeking SOP had not had a documented review since being approved in 2015 and the perinatal consent SOP had not had a documented review since being approved in 2017. This poses the risk of staff not following current HTA standards and guidelines. *(*See *Advice* item one*)*	
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	The Inspection team were not assured all risks are assessed on a regular basis. Not all HTA reportable incidents had been identified and risk assessed. Additionally, there was no manual handling risk assessment relating to the use of the bottom shelf of the refrigerated storage units. This means there was insufficient mitigation in place to minimise the risk to bodies of a reportable incident.	**Major (cumulative)**
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	Some risk assessments lack detail regarding actions taken to mitigate risks to bodies of a HTA reportable incident. Additionally, it is not always clear what actions need to be taken, who is responsible for each action or the timeline for completing these. This means identified risks may not be mitigated in a timely way.	
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	Whilst three identifiers were obtained from family members before a viewing was undertaken, this was not checked against the written records taken at the time of booking for assurance the identifiers match those detailed on the body. This poses the risk of the viewing of the wrong body.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Access to the mortuary was gained via swipe card and keys. The inspection team were not assured there was suitable oversight of the keys used to access the mortuary. During the inspection, unrestricted windows were identified. These opened onto a courtyard from intermittently occupied areas within the mortuary. The door between the post mortem suite and access corridor used by porters and funeral directors was not always locked out of hours. This poses the risk of unauthorised access to restricted areas within the mortuary.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst audits of swipe card access records against CCTV footage are scheduled to be carried out every month, these have not been carried out as scheduled due to delays in the information being shared with the mortuary team. This means there is insufficient oversight of the activity undertaken by authorised staff, visitors and contractors who have a legitimate right of access.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

c) Staff are assessed as competent for the tasks they perform	Not all staff are assessed as competent for the tasks they perform under the licence. Porters do not receive formal, documented competency assessments.	**Minor**
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.	The porters access to the mortuary used for the transfer of bariatric bodies was poorly lit and there was a large hole in the pathway. Additionally, the roof was leaking into an interior corridor leading to the body store. This poses the risk of accidental damage to a body during transfer.	**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.	C1(f)	Whilst there was a timeframe for family members to change their minds outlined in the SOPs and policies for consent, this was given as 18 hours. The consent forms used for adult PMs give a cooling off period of 24 hours. The DI should review the documents governing consent to ensure information is consistent and reflective of staff practice.
2.	GQ1(a)	The DI should implement systems and processes to ensure there is a proactive approach to document reviews. This will mean staff are working within current best practice frameworks and reduce the risk of deviation from SOPs.

3.	GQ6(c)	The DI should expedite existing plans in place for a staffing review and recruitment.
4.	T1(g)	Whilst staff document when tissue slides are taken offsite for analysis, and their return, the DI should consider introducing formal systems and processes to ensure any delays in return of slides are identified and followed up.
5.	T2(d)	Whilst there is a system in place for the recording of disposal of tissue blocks and slides, this is the responsibility of one member of staff. The DI should consider training an additional member of staff to oversee the traceability of tissue taken during post mortem to ensure there is service resilience.
6.	PFE2(e)	Whilst the Inspection team are assured the toxicology fridge is only used for short term storage before transfer for analysis, it does not have an alarm to alert staff to temperature excursions. The DI is advised to maintain oversight of the length of time samples are stored and ensure it is attached to a temperature monitoring system should samples be stored out of hours.
7.	N/A	Whilst staff across the BSPS (Berkshire and Surrey Pathology Services) network do share some information, this is on an ad hoc, informal basis. The DI should expedite existing plans for formal meetings to take place with all key staff across the network. This will support the sharing of best practice and shared learning from incidents in addition to contingency planning to support system wide resilience.

Background

Wexham Park Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in September 2019. The establishment is part of a network of mortuaries providing licensed activity across Surrey and Berkshire.

Since the previous inspection, there have been no significant changes in licensed personnel. Building works have been carried out within the mortuary including the refurbishment of the Post Mortem room, and an extension to the body store to provide additional capacity.

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 applicable 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, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff, porters and consent seekers.

Visual inspection
The inspection included a visual assessment of the establishment including body storage areas, post-mortem/preparation rooms and viewing rooms. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of five bodies from refrigerated and frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified. Audits of traceability were conducted for tissue blocks and slides from four post mortem examinations. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, mortuary manager, APT, pathologist, mortuary porter, bereavement midwife and quality lead.

Report sent to DI for factual accuracy: 17/10/2023.

Report returned from DI: 19/10/2023

Final report issued: 20/10/2023

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: 26 June 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.