Site visit inspection report on compliance with HTA licensing standards
Inspection date: **17 – 18 September 2019**

Wexham Park Hospital

HTA licensing number 12323

Licensed under the Human Tissue Act 2004

Licensed activities

The table below denotes whether the site is licensed to carry out an activity and whether or not the activity is currently carried out in that area.

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
Wexham Park Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	-
Accident and Emergency (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, 10 minor shortfalls and five major shortfalls were found against the 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
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.	Identification of bodies for viewings is performed using only two identifiers of the deceased that are provided verbally by the relatives upon arrival at the mortuary.	**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.	The mortuary premises have not been maintained to a sufficient standard. • The floor coverings in the body store and post mortem (PM) room are in poor condition and have split in several areas. This presents a trip hazard and means that the floors cannot be cleaned and disinfected adequately. • There are areas of exposed wood in the body store and PM room. This means that there are porous surfaces that cannot be cleaned and disinfected adequately. • There is standing water in the drains in the PM room. This presents a health and safety risk. • There are areas of rust on the metal wall plates in the PM room.	**Major**
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).	The door between the viewing room and the body store does not provide adequate access control. • The lock on the door can be opened from the viewing room. This means that visitors could gain unauthorised access to the body store. • The door has a clear glass window pane. This means that visitors in the viewing room could see into an area of the body store.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.	Freezer storage capacity is not sufficient to meet needs. This has resulted in some bodies not being transferred to frozen storage when required.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.	The establishment cannot provide evidence that the PM room ventilation system has been serviced regularly. The most recent ventilation records available for review during the inspection were from February 2017. This presents a health and safety risk to staff, particularly given that high risk PM examinations are undertaken at the establishment.	**Major**

Minor shortfalls

Standard	Inspection findings	Level of shortfall
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.	There is no formal training programme in the requirements of the HT Act and the HTA's codes of practice for staff who seek consent for paediatric/perinatal PM examinations.	**Minor**
b) Records demonstrate up-to-date staff training.	There are no consent training records for staff who seek consent for paediatric/perinatal PM examinations.	**Minor**
d) Competency is assessed and maintained.	There is no evidence that staff competency is assessed or maintained for seeking consent for paediatric/perinatal PM examinations.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	The procedure for transferring bodies into and out of the top and bottom fridge and freezer spaces has not been documented or risk assessed. The mortuary trolley cannot reach these storage spaces and the establishment's practices for using these spaces present health and safety risks to staff and a risk of accidental damage to bodies.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.	Licensed activities in the A&E department are not included in the establishment's governance framework for the HTA licence. Staff from this department are not included in the establishment's governance meetings for the HTA licence. There are no Persons Designated (PDs) nominated to help to oversee licensed activities in this department.	**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.	Documented risk assessments of licensed activities cover health and safety risks to staff but do not cover risks to the dignity and integrity of bodies and tissue.	**Minor**
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.	The establishment's procedure for use of overshoes to maintain separation of clean, dirty and transitional areas of the mortuary are not always followed by staff and visitors.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning.	There is no cleaning and decontamination procedure or schedule of cleaning for the mortuary.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in a good condition and appropriate for use: i. fridges / freezers ii. hydraulic trolleys iii. post mortem tables iv. hoists v. saws (manual and/or oscillating)	There are some areas of rust on trolleys, PM equipment (such as scissors and saws) and clinical waste bins. This means that these items of equipment cannot be cleaned and disinfected adequately.	**Minor**
d) Staff have access to necessary PPE.	Although staff have access to face masks for use in the PM room, they have not been fit-tested for these masks and no alternative personal protective equipment is available (for example, vented hoods).	**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(a)	The DI is advised to document the procedures for ensuring on-going communication with the coroner's office regarding consent for storage and use of tissue samples.

2.	GQ2(c)	The DI is advised to ensure that all audits of tissue samples are documented. The DI is also advised to review the frequency of audits of licensed activities following changes to the establishment's procedures or licensing standards.
3.	GQ4(b)	The DI is advised to ensure that all relevant staff are aware of the procedure to make amendments to written records, for example to the mortuary register.
4.	T1(c)	The DI is advised to ensure that identification procedures clearly describe how information should be crosschecked between mortuary records, identification bands on the deceased and information provided by funeral directors. This will help to strengthen the procedure for identification of bodies in cases where several records need to be crosschecked to ensure that a minimum of three identifiers of the deceased are used.
5.	T1(d)	The DI is advised to strengthen the system for identifying bodies with same or similar names, for example by using visual cues on bodies, fridge/freezer doors and in the mortuary register.
6.	PFE2(a)	The DI should review the practice of writing identifiers of the deceased on body bags. This practice presents a risk that identification checks may be performed using the information written on the body bag instead of using the identification bands attached to the body.

Background

Wexham Park Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased, and relevant material, for use for scheduled purposes.

Wexham Park Hospital has been licensed by the HTA since June 2007. This was the fourth site visit inspection of the establishment; the most recent previous inspection took place in November 2015.

There have been some changes to the licence arrangements since the last inspection, this includes changes to the DI and PDs. There have been no significant changes to the activities carried out under the licence since the previous inspection.

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 licensing standards for the PM sector were assessed (revised HTA standards 3 April 2017).

Review of governance documentation
The inspection included a review of the establishment's governance documentation relating to licensable activities. This included policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, consent documentation and staff job descriptions and training records.

Visual inspection
The inspection included a visual inspection of all areas covered by the licence including the mortuary body store, PM room, viewing room and the histopathology laboratory. A visual inspection was also completed in the Maternity and Gynaecology departments; however, no licensed activities were being conducted in the departments at the time of the inspection.

Audit of records
Audits were conducted for six bodies in refrigerated storage and three bodies in freezer storage. These audits included adult and paediatric cases admitted from the community and hospital. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. No discrepancies in the traceability of these tissues were found.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed. This included interview with the Quality Manager, Anatomical Pathology Technologists, Mortuary Manager, Chief Biomedical Scientist, Bereavement Manager, Pathologist, Portering Supervisor, staff seeking consent for PM examinations and the DI.

Procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes
Home Office PM examinations may be conducted at this establishment. Tissue samples and organs retained for police purposes are sent to other establishments for analysis. Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings in relation to Home Office PM examinations and/or police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 09 October 2019

Report returned from DI: 14 October 2019

Final report issued: 17 October 2019

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: 21 September 2020

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 site visit 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 site visit.

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

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