Inspection report on compliance with HTA licensing standards
Inspection date: **1 June 2023**

Arrowe Park Hospital

HTA licensing number 12027

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 **Arrowe Park Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Maternity			*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 Arrowe Park Hospital ('the establishment') had met the majority of the HTA's standards, seven major and six minor shortfalls were found against standards for 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
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment have a schedule of audits, the schedule does not include audits of all mortuary activities for example, security audit and viewing procedure.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Not all staff who are involved in mortuary duties are appropriately trained: • The porters training package does not include procedures for admitting bodies, viewing bodies out of hours and of HTA reportable incidents (HTARI). • There is no training in place for bed managers and site co-ordinators who facilitate out of hours viewings.	**Major**
c) Staff are assessed as competent for the tasks they perform	There is no system for assessing and recording competency of portering staff in the mortuary procedures they perform. Bed managers and site co-ordinators who prepare deceased for viewing out of working hours have not been assessed by the establishment as competent to undertake this activity in accordance with the establishment's procedures.	**Major**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		

a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The inspection team identified near-miss incidents under the HTARI category 'major equipment failure' reported on the Trust incident system since the previous inspection which have not been reported to the HTA. Porters and maternity staff are not aware of incidents that must be reported to the HTA.	**Major**
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	All procedures relating to licensed activities have not been risk assessed. These include but are not limited to: • major equipment failure. • incident leading to unplanned closure of mortuary/inability to deliver services. • serious security breach. • lone working in the mortuary in and out of hours. This is not an exhaustive list of the risks not assessed and, to fully address this shortfall, the establishment should review all risk assessments relating to licensed activities to ensure that all risks have been identified.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	CCTV is in operation at mortuary access points, however, the body store is not covered. Authorised individuals are required to swipe out when leaving the internal transfer area in the body store only. There was no evidence available for review that follow up with individuals not following this procedure was occurring. Facilities staff are the point of contact if the fridge and freezer alarms are triggered out of hours. Mortuary staff are unaware of how facilities staff are accessing the mortuary to check the fridge and freezers, and there is no system for recording who has been in the body store, the nature of their business and when they arrived and left. Whilst swipe card access lists are reviewed and a random number of these are reviewed against CCTV footage, mortuary staff do not have oversight to effectively audit individuals accessing the mortuary and ensure oversight of visitors and contractors who have a legitimate right of access. Access to the mortuary from the hospital corridor and into the pathologist office is with a key. There were no records available to review where the keys were stored, who had access to these keys and the number of keys in circulation.	**Major**
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 mortuary and maternity staff do not manually challenge the lower alarm trigger point on a regular basis. This does not provide assurance that the alarm will trigger when temperatures deviate from the expected range and that the call out procedure works. *Refer to shortfall PFE1e for further detail.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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.	Some Standard Operating Procedures (SOPs) relating to mortuary activities are not reflective of current practice for example: • Viewing of deceased. • Disposal of tissue. Not all SOPs include all practices that are undertaken by staff. These include, but are not limited to, SOPs detailing the process for: • Body condition checks of deceased. • Mortuary business continuity plan. *See advice item 2*.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Visiting pathologists who undertake post mortem (PM) examinations do not sign that they have read and understood the applicable HTARI categories and establishment's risk assessments.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is system for flagging up same or similar names of the deceased	The current procedure of attaching a coloured band to the fridge tray for flagging up same or similar names is not being followed. The inspection team also found during the body audits undertaken that same or similar name magnets had also not been used as per procedure.	**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	Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: • Minor areas of exposed wood on the doorframes; • Minor areas of exposed plaster; • Debris in the drain in the post mortem room; and • Leaking sink in the post mortem room.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Although there is demarcation of a transitional area between the post mortem (PM) room and the body store, bodies have to be transferred from the PM room on trolleys into the body store area to place them back into refrigerated storage. This area is in constant use by both mortuary staff and funeral directors when they collect and bring bodies to the mortuary. No cleaning or decontamination of the body store area takes place between the movement of the bodies and staff from the PM room following or during PM examinations.	**Minor**
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	The trolleys have multiple areas of rust. This means that it is difficult for staff to adequately clean and disinfect this equipment.	**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.	C2a	The DI is advised to ensure that the new training package sent to core staff for perinatal PM examination consent seeking is completed and returned within the timeframe that has been set.
2.	GQ1a	The DI is advised that although a procedure is in place for the disposal of tissue there is no specified timeframe for these audits to be conducted. There is a risk that tissue may not be disposed of as soon as reasonably possible.
3.	GQ4b	The DI is advised to ensure that staff are aware of how to correct errors in the mortuary registers to ensure that traceability is maintained.
4.	GQ5a	The DI is advised to ensure that a representative of maternity staff that seek consent for perinatal PM examination attend or receive minutes from governance meetings that discuss HTA matters. The DI is advised to have signage on the maternity wards and in the mortuary of applicable HTARI categories and personnel to contact as an aide memoire for staff.
5.	T1c	When transferring babies from maternity a sticker is added to the body bag. The DI is advised to add the information on the sticker to the identity band to reduce the risk of the sticker being lost.
6.	T2b	The DI is advised to liaise with the Coroner regarding the use of Next of Kin on the family wishes form. The DI is also advised to liaise with the Coroner to clarify with the families their expectations on what is meant by retaining material for medical record. The DI is advised to liaise with the Coroner a more robust method of communicating with the establishment the end of the Coroner's jurisdiction.
7.	PFE2f	The DI is advised to record and review trends in storage temperatures. This may help to identify trends and the extent of any variations in storage temperatures.

Background

Arrowe 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.

Arrowe Park Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2018.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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 and post-mortem room, records servicing of equipment, audits, risk assessments, meeting minutes, ventilation record, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room, viewing room and maternity.

Audit of records

Audits were conducted for three bodies in refrigerated storage and one in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies found.

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. Whilst one minor discrepancy was found, this was not sufficient to amount to a shortfall but oral advice was given to the establishment at the time of the inspection.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, anatomical pathology technician (APT), pathologist, portering staff and maternity staff.

Report sent to DI for factual accuracy: 26 June 2023

Report returned from DI: 10 July 2023

Final report issued: 7 August 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:

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.