Inspection report on compliance with HTA licensing standards
Inspection date: **23rd and 30th June 2022**

Weston General Hospital

HTA licensing number 30013

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
Weston General Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Weston General Hospital ('the establishment') had met the majority of the HTA's standards, 2 major and 7 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	The scope of the audit schedule does not include sufficient horizontal audits to cover all licensed activities. No audits of PM documentation are carried out and there are no vertical audits included in the schedule. *(See advice item 1)*	**Major**
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 process for releasing a body which has been under the jurisdiction of the coroner includes a check of three identifiers on the deceased's wristband against the coroners release form, which is sent to the mortuary directly. This check is carried out by an APT at the time the body is released. However, funeral directors only verbally confirm the name of the deceased on arrival to the mortuary. Although three identifiers are checked on the deceased when preparing a body for viewing, the procedure does not include a final check using a minimum of three points of identification of the deceased provided by the relatives prior to them entering the viewing room. The use of less than three separate identifiers when identifying bodies, presents a risk of releasing or viewing the wrong body.	**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.	Standard Operating Procedures (SOPs) relating to mortuary activities lack sufficient detail and/or are not reflective of current practice. These include, but are not limited to, SOPs detailing the process for: - Body Admission Storage and Handling; - General Autopsy; and - Mortuary Seasonal escalation Plan. This is not an exhaustive list of the SOPs that need to be amended. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they reflect current practice.	**Minor**
GQ2 There is a documented system of audit		

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The establishment holds tissue taken at post mortem examinations carried out prior to 1st April 2019. Since this date all tissue removed at post mortem examination has been sent off site. Although the tissue held at the establishment was audited in 2018 as part of the follow up action from the previous HTA inspection, no subsequent audits of this tissue have taken place or are scheduled to take place in the future. During the tissue traceability audit a discrepancy was identified by the inspection team.	**Minor**
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	Bodies are admitted to the mortuary out-of-hours by Funeral Directors appointed by the Coroner. Although the mortuary delivers a training package to some funeral director staff on an ad-hoc basis, there is no system in place which ensures all funeral director staff who admit bodies have received this training.	**Minor**
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 establishment has a recognised process for reporting incidents to the HTA and staff are aware of the different categories of incident which need to be reported. However, the local mortuary incident log provided to the inspection team included near miss incidents which should have been reported to the HTA. This indicates that staff do not know to report near miss incidents to the HTA.	**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	Fridge temperatures are monitored by an external company who will contact mortuary staff via the hospital switchboard if the fridge temperatures go out of range. The mortuary staff do not manually challenge the body store alarms on a regular basis. This does not provide assurance that the call-out procedure is effective.	**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 hydraulic trolley in the body store area has small patches of rust.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.	The service report for the post mortem room ventilation system states that the necessary ten air changes per hour are provided. However, the service report (dated October 2021) identified a number of urgent and/or immediate maintenance actions to be taken to safeguard the functioning of the ventilation system. These maintenance actions have not been taken.	**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.	GQ2(a)	The DI is advised to use these procedural audits as an opportunity to review SOPs to see if practice reflects what is written in the SOP for each activity
2.	GQ2(b)	The DI is advised to consider incorporating all mortuary audits into the Pathology Department Audit Schedule such as the mortuary security audits and the weekly body audit to facilitate the monitoring and escalation of non-

		conformances.
3.	PFE1(e)	While there is CCTV to monitor access to the mortuary, the DI is advised to introduce a visitor's book to record contractors and visitors who enter the mortuary.
4.	PFE2(a)	The mortuary is covered by CCTV which can be accessed by the mortuary and the trust security team. The DI is advised to seek written assurances from the security team regarding the access controls to this footage.
5.	PFE2(i)	The DI is advised to expand the scope of the Seasonal Escalation Plan to include all contingency arrangements, to include other scenarios such as fridge failures.

Background

Weston General Hospital has been licensed by the HTA since April 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2017.

Since the previous inspection, the establishment has ceased storing tissue taken at post mortem and these samples are not sent off site for analysis and subsequent disposal or retention.

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

Out of a total of 72, the following standards were **not** covered during the inspection because the standards were not applicable to the establishment:

C1a,nd T2(d). C1(a)-(g), C2 (a)-(d) and T2(d)

The remaining 60 HTA licensing standards (standards published 3 April 2017) were assessed.

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, ventilation reports, audits, risk assessments, meeting minutes, incidents and staff training records.

Visual inspection

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

Audit of records

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

Audits of traceability were conducted for tissue blocks and slides from two PM cases for which tissue was held on site, including audits of the consent documentation for the retention of these tissues. One discrepancy was identified. A further 2 audits were conducted for tissue taken at PM and sent off site which included an audit of the consent documentation and paperwork to track the tissue to the external laboratories. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, trainee APT, portering staff, and a pathologist.

Report sent to DI for factual accuracy: 21st of July 2022

Report returned from DI: 16th August 2022

Final report issued: 17th August 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]/[Virtual Regulatory Assessment] Report.

Date: 13th April 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.