Inspection report on compliance with HTA licensing standards
Inspection date: **14 and 15 July 2022**

Glan Clwyd Hospital

HTA licensing number 12153

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 **Glan Clwyd Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	*Carried out*	-
Satellite site **Ysbyty Gwynedd Bangor**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	*Carried Out*	Carried Out
Maternity	-	-	-

A&E	-	*Carried out*	-
Satellite site **Wrexham Maelor Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	*Carried out*	*Carried out*
Maternity	-	-	-
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 Glan Clwyd Hospital ('the establishment') had met the majority of the HTA's standards, 7 major and 4 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
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The establishment does not have a procedure for carrying out and recording condition checks of bodies in storage, or the actions taken to expedite release from the mortuary and/or prevent deterioration to the body. At the time of the site visit there was one body which had been in refrigerated storage for over 60 days with no accompanying record of condition checks nor actions taken. *(See shortfall under PFE2(c) regarding freezer capacity)*	**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	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 visitors prior to them entering the viewing room.	**Major**
d) There is system for flagging up same or similar names of the deceased	The establishment has a written procedure for flagging up same or similar names. However, this system has not yet been fully implemented across the sites. The inspection team observed at least one occurrence at each site where two or more of the deceased with the same name had not been highlighted in accordance with the written procedure.	**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.	The establishment does not have a system in place to review records of access to the mortuary to ensure that it is limited to those with a legitimate right of access. Furthermore, the establishment does not have a register to record visitors and contractors who enter the mortuary sites. *(See advice item 2 below)*	**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	The establishment does not have sufficient freezer storage capacity to meet the need for long-term storage of bodies. At the time of the inspection all freezer storage was in use and there were at least two bodies awaiting transfer to the freezer. Although the establishment has a fridge unit which can be converted into freezer storage to provide a further four spaces, this unit is currently used as a containment unit for cases arriving out of hours from the community in a state of decomposition or infestation. There is no freezer space for bariatric bodies.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	<u>Satellite Site - Wrexham Maelor</u> A former viewing area has been converted into a cold store room which is used for bariatric bodies. The refrigeration unit in this room leaks water onto the floor and mould has formed on the ceiling and walls which cannot be removed.	**Major**

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	Hub Site - Glan Clwyd The external storage unit is linked to a remote temperature monitoring and alarm system but the alarm and call out procedure are not tested. The standalone fridge for early pregnancy remains is not alarmed. Satellite Site - Ysbyty Gwynedd Bangor The fridge used to store pregnancy remains and perinatal bodies has an audible alarm but it is not linked to the remote monitoring and alarm system. This means that there would be a delay in identifying and rectifying a fridge failure if it occurred out-of-hours.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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 has a robust system for managing tissue taken at post mortem examination which includes ongoing checks to ensure any outstanding instructions for disposal are followed up in a timely manner. However, the retained tissue is not subject to regular wholescale audits.	**Minor**

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	The establishment has recently implemented a comprehensive competency assessment framework for mortuary staff. At the time of the inspection, most staff had completed the competencies, however some had not. On occasion the hospital site team need to access the mortuary and assist with out-of-hours viewings. Although they are accompanied by trained porters, there is no specific mortuary training in place for members of the hospital site team. At the Wrexham Maelor Satellite, funeral directors access a small body store area to admit bodies to the mortuary out-of-hours. Although training is provided on an ad-hoc basis, there is no formal arrangement or record of training for these funeral directors.	**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.	<u>Hub Site - Glan Clwyd</u> The floor in the Post Mortem room has split along a central seam allowing slight water ingress and egress which prevents full decontamination. <u>Satellite Site Wrexham Maelor</u> The coating on the floor in the main body store area is showing signs of wear. This is exposing the concrete beneath which is of a porous nature, making it difficult to clean and decontaminate.	**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	A number of the hydraulic trolleys across the three sites have areas of rust requiring attention.	**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(g)	The DI is advised to nominate HTA representatives (Persons Designated) in the Accident & Emergency departments and to extend the invitation to the HTA governance meetings to these representatives.
2.	GQ2(a)	The DI is advised to introduce regular audits of mortuary access across all sites to include a crosscheck of legitimate rights of access to the mortuary against frequency, duration and patterns of attendance to ensure access is in line with the purpose for which it was granted. (*See shortfall under PFE1(e)*)
3.	GQ6	The establishment has an extensive suite of risk assessments and the DI may wish to consider consolidating some of the risk assessments to facilitate staff awareness. For example, the risk assessments RA 39-42 all relate to viewing of the deceased.
4.	T1(c)	The DI may wish to consider the introduction of a standard release form, which can be used by funeral directors for the release of bodies. This form could include the relevant identification information to check against the mortuary register and identification band on the body before being released.
5.	PFE1(d)	The rear mortuary door at the hub site opens onto a courtyard area secured by gates which are accessed by swipe card. The door has a pin code entry system. The DI is advised to ensure that the pin code is changed

		regularly until the planned upgrade to swipe card access is installed.
6.	PFE2(e)	The establishment has a temporary storage unit which has recently been decommissioned. The DI is advised to ensure that if it is brought back into use it is connected to the remote temperature monitoring and alarm system.
7.	PFE2(i)	The DI is advised to clarify the scope of the contingency plan within MORT.0098 (Mortuary Contingency plan) to confirm that these arrangements apply in the event of a power failure.

Background

Glan Clywd 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 September 2017.

Since the previous inspection, post mortem activity has ceased at both the Wrexham Maelor and Ysbyty Gwynedd Bangor satellite sites. All post mortem activity is now carried out at the Glan Clwyd Hub site and the licence for the making of a post mortem has been removed from the two satellite sites.

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

Visual inspection

The inspection included a visual inspection of all three sites including the mortuary body stores and viewing rooms as well as the PM room at the hub site.

Audit of records

Glan Clwyd Hospital (Hub) - Audits were conducted for three bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the paper mortuary register. No discrepancies were found. Audits of traceability were conducted for tissue blocks and slides from four PM cases where tissue was held on site, including audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Wrexham Maelor (Satellite) – Audits were conducted for three bodies in refrigerated storage. Body location and identification details were crosschecked against the information on the electronic mortuary register. No discrepancies were found.

Ysbyty Gwynedd Bangor (Satellite) – Audits were conducted for two bodies in refrigerated storage and one in freezer storage. Body location and identification details were crosschecked against the information on the electronic mortuary register. One minor discrepancy was identified but traceability of tissue was not affected.

Meetings with establishment staff

Staff carrying out processes under the licence across the different sites were interviewed including the DI, mortuary manager, APTs, portering staff, and pathology staff.

Report sent to DI for factual accuracy: 8th of August 2022

Report returned from DI: 15th of August 2022

Final report issued: 16th of 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 Report.

Date: 3 January 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.