Inspection report on compliance with HTA licensing standards

Inspection date: **06 and 07 November 2024**

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*
A&E	-	*Carried out*	-
Satellite site	Not licensed	Licensed	Licensed

Ysbyty Gwynedd Bangor			
Mortuary	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite Site Wrexham Maelor Hospital	Not licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
A&E	-	*Carried out*	-

Summary of inspection findings

The HTA found the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation. At the time of our inspection the Designated Individual (DI) had very recently stepped down from the role, and no application for a successor had been received from the establishment. An application for a successor was received after the inspection team left site. The applicant has been interviewed by the HTA and found to be suitable.

Although the HTA found that Glan Clwyd Hospital ('the establishment') had met the majority of the HTA's standards, nine major and two minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. Five of the Major shortfalls relate to findings from the last inspection. At the inspection feedback meeting, the HTA inspectors expressed their concerns that adequate steps had not been taken to address these findings in the intervening period and to embed suitable practices at the establishment. A similar issue was identified in standards GQ1(c), GQ3(c), T1(c), (d) and PFE1(e) at the previous inspection carried out in July 2022.

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
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 initial or refresher training available for those responsible for seeking consent for adult post mortem examinations (PMs). However, the establishment has not received a request for an adult hospital consented PM for at least two years.	**Major (cumulative)**
d) Competency is assessed and maintained	The establishment does not have a system in place for assessing staff as competent with the HTA requirements when seeking consent for adult PMs.	
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) lack detail and do not reflect best practice guidance. These include, but are not limited to, SOPs detailing the process for: - Viewing of bodies - Post-Mortem Examinations - Security and access to the mortuary This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Major**

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst there is a written procedure in place relating to condition checking, staff only record the condition of a body on admission, at PM examination and on release. This is not reflective of the SOP. During the inspection bodies were identified that had been in refrigerated storage for longer than 30 days and were starting to deteriorate.	**Major**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There is no Persons Designate for every area that carries out HTA licensed activity. The inspection team were not assured that the DI has oversight of regulated activities on the maternity ward and emergency department.	**Major (cumulative)**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst matters relating to HTA licensed activity are discussed at regular governance meetings, these are not documented.	
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	The inspection team were not assured all staff involved in mortuary duties were appropriately trained. Site teams and Funeral Directors who carry out mortuary duties out of hours do not receive training. Furthermore, whilst all porters involved in mortuary duties receive initial training, they do not receive regular documented refresher training.	**Major (cumulative)**

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. Site teams and Funeral Directors do not receive formal, documented competency assessments. Furthermore, no documents were available for review indicating Porters who undertake mortuary duties receive a regular assessment of competency, following the initial competency assessment undertaken during their induction.	
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Whilst there is a system in place to track the location of bodies in storage, changes in storage location are not always updated on the individual patient record and the electronic mortuary register at Wrexham Maelor hospital. Furthermore, some of the information on the whiteboard at Glan Clywd hospital used for recording the location and identification of bodies had rubbed away leaving it illegible. This poses the risk of an incident relating to the identification of a body.	**Major (cumulative)**
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	At Glan Clwyd Hospital and Ysbyty Gwynedd Bangor three forms of identification are completed on the viewing form. However, these are not reflective of the information provided by the family when they attend the mortuary for a viewing. At Wrexham Maelor Hospital whilst three forms of identification are requested from the family. Staff list the type of identification obtained but the details are not recorded on the viewing form. This poses the risk of a viewing of the wrong body.	

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	Whilst all access and egress points to the mortuary are covered by CCTV, the feed is not routinely audited against swipe access records. Additionally, whilst a recent review of staff with mortuary access has been undertaken at Wrexham Maelor hospital, this has not yet been undertaken at Glan Clywd Hospital and Ysbyty Gwynedd Bangor. Furthermore, visitors are not asked to sign in and out of the mortuary, this includes staff entering the mortuary to undertake activity out of hours. This poses the risk of insufficient oversight of contractors and visitors to the mortuary, and a delay in the identification of a serious security breach incident out of hours. *See advice item one.*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
g) Bodies are shrouded or in body bags whilst in storage	The Inspection team identified several bodies at Glan Clwyd Hospital and Ysbyty Gwynedd Bangor where there was insufficient shrouding and bodies were not fully covered whilst in storage.	**Major**
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 trays used to store bodies in the contingency storage unit are not compatible for use with the hydraulic trolleys. This poses the risk of accidental damage to a body during transfer, and staff sustaining musculoskeletal injury.	**Major**

Minor 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		
d) There is system for flagging up same or similar names of the deceased	The establishment has a written procedure in place for flagging same or similar names, However, the inspection team identified inconsistencies in the highlighting of the deceased with a same or similar name in accordance with the written procedure at Glan Clywd and Wrexham Maelor Hospitals. This poses the risk of a viewing or release of the wrong body incident.	**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	Damage has been sustained to the housing for pipework in the body store at Ysbyty Gwynedd Bangor, which has led to the exposure of the wooden housing. Additionally, a wooden measuring stick is in use at Glan Clwyd hospital and wooden door wedges are in use across the three sites. This poses the risk of ineffective cleaning and decontamination.	**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.

DI and CLH/LH suitability

At the time of the inspection there was no DI in post as the previous DI has stepped down from her role. Whilst a replacement had been identified, HTA had not received a licensing application or been informed of this change before the inspection.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ3(c)	The DI is advised to expedite the assessment of mortuary staff competency once a mortuary manager has been recruited and is in post.
2.	GQ5(d)	Whilst porters are kept up to date with changes to practice within the mortuary. The DI is advised to involve porters in the outcomes and findings of investigations for relevant incidents.
3.	GQ6(a)	The DI is advised to consider the introduction of a “man down” alarm for staff to use whilst undertaking viewings.
4.	PFE1(d)	Whilst the fridge compressor units are in a secure area which is monitored by CCTV. The DI is advised to consider the addition of a tamper proof device to the external components to further mitigate the risk of interference with the control switches.
5.	PFE1(e)	The DI is advised to consider changing the intruder alarm and keypad codes on a regular basis, to further mitigate the risk of a security incident. The frequency and threshold for these changes should be added to the security SOP.
6.	PFE2(e)	The DI is advised to add alarm testing of fridges out of hours to the existing fridge temperature testing schedule to ensure the system works as expected during times when the mortuary is closed.
7.	PFE3(f)	The systems and equipment within the mortuary are subject to regular testing and servicing. However, not all records are kept within the mortuary and are only available upon request. The DI is advised to

		request copies of all maintenance, servicing and repair reports so that they are easily accessible to mortuary staff for review and monitoring purposes.

Background

Glan Clwyd Hospital has been licensed by the HTA since 2007. This routine unannounced inspection was the fifth inspection of the establishment; the most recent previous inspection took place in July 2022.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence. However, there was due to be a change in key personnel with the DI stepping down before our inspection and the appointment of a successor being undertaken. Additionally, the establishment was in the process of recruiting a mortuary manager.

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, records of servicing of

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

Visual inspection

The inspection included a visual assessment of the hub and both satellite sites named on the licence including, body storage areas in the mortuaries, the PM room at the hub site, viewing rooms and tissue storage areas. The inspection teams observed the processes for admission and release of bodies within the mortuary.

Audit of records

Glan Clwyd Hospital

Audits were conducted onsite of four bodies from refrigerated storage, and one body stored in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. A minor discrepancy relating to the transcription of information from the mortuary register to the mortuary whiteboard was identified. This was rectified immediately.

Audits of traceability were conducted for tissue blocks and slides from three coronial cases, these included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Ysbyty Gwynedd Bangor

Audits were conducted onsite of two bodies from refrigerated and one body stored in long term frozen storage, which had been transferred from the hub site. Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. No discrepancies were identified.

Wrexham Maelor Hospital

Audits were conducted onsite of four bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the Specialist services managers, Pathologist, Senior APT, mortuary assistant, porters, tissue lead, and bereavement midwife.

Report sent to DI for factual accuracy: 16/12/2024

Report returned from DI: 14/01/2025

Final report issued: 14/01/2025

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: 11 June 2025

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.