Inspection report on compliance with HTA licensing standards
Inspection date: **3 & 4 April 2024**

Glangwili General Hospital
HTA licensing number 12136

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 **Glangwili General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Glangwili General Hospital ('the establishment') had met the majority of the HTA's standards, three cumulative major, three major, and two 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	Whilst there is a documented schedule of audits that include checking swipe card access records against authorised staff lists, audits are not carried out against the CCTV.	**Cumulative Major**
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and enable timely disposal of tissue where consent has not been given for continued retention.	The establishment are currently storing post mortem (PM) blocks and slides in the mortuary and as there is no regular audits of the tissue, there is no assurance that tissue is being disposed of as soon as reasonably possible. This poses a risk that staff are not disposing of tissue in a timely manner where consent has not been given for continued retention. *Refer to shortfall against standard T2 (b) for further detail.*	

Standard	Inspection findings	Level of shortfall
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 establishment did not provide any completed training records for porters involved in mortuary activities and informed the inspection team that refresher training for porters does not take place.	**Cumulative Major**
c) Staff are assessed as competent for the tasks they perform	Whilst mortuary staff have been trained and have completed previous rolling programmes of competency assessment, locum/bank staff were not up to date with the current cycle of competency assessment in key tasks. Competency assessments reviewed by the inspection team lacked specific details. For example: • Staff describing identification procedures for viewings did not make it clear what the three identifiers could be, what they should be checked against prior to a viewing taking place and the process for checking these identifiers with the family prior to viewing.	

Standard	Inspection findings	Level of shortfall
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	Whilst staff know how to identify incidents and report them internally; a review of the incident log by the inspection team identified several incidents that were not reported to the HTA. These incidents included HTA reportable incident (HTARI) categories which fall under 'serious security breach', 'accidental damage to a body' and 'major equipment failure.'	**Major**

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly and monitored		
c) Significant risks, for example to the establishment's ability to deliver postmortem services, are incorporated into the Trust's organisational risk register.	The inspection team were not assured that the risks on the Corporate Risk Register have been actioned in a timely way. Examples include but are not limited to: • Risk of unauthorised access to the mortuary premises due to inadequate security • Lack of bariatric storage space • Reduced delivery of mortuary services due to staff having to undertake bereavement service duties. The above risks have been on the risk register since 2022. There is an increased risk of potential serious incidents due to the delay in addressing these risks.	**Major**

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body store area(s) and PM room and the use of CCTV to monitor access).	There is CCTV in the mortuary, however there are some blind spots which block the view to some parts of the facility. Furthermore, although there is a live feed of the CCTV, staff are unable to access CCTV recordings directly.	**Cumulative Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Mortuary management do not have direct control of granting and removing access to the mortuary on the swipe card system. This is controlled by a different department in the hospital. There has been an instance when the swipe card access control failed resulting in all swipe cards that had previously been restricted, having mortuary access reinstated. This was picked up during an audit and has since been corrected. Whilst swipe card access lists are reviewed and updated by the regional mortuary manager, with a different department having overall control, there is no assurance that security arrangements fully protect against unauthorised access. Furthermore, there have been several incidents during working hours where unauthorised hospital staff have used their swipe card to gain access the mortuary, including doctors visiting for mortuary business. Unauthorised access has not occurred outside working hours as security would be notified due to an intruder alarm that activates if anyone accesses the mortuary.	

Standard	Inspection findings	Level of shortfall
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	There is insufficient freezer and bariatric storage capacity to meet needs. There are four standard size freezer spaces for the long-term storage of bodies over three hospital sites. There is no functional bariatric storage which means that multiple hospital sites which operate under the Health Board are relying on a bariatric fridge bank at another licensed establishment.	**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 SOPs are not detailed enough to ensure uniformity between staff following procedures. For example: • The SOP for PM procedure does not state the current practice for evisceration where the pathologist conducts an external examination of the deceased prior to instructing the APT to proceed with evisceration • The SOP that details the same/similar name procedure does not include the placing of a same/similar name wristband on the deceased and practices on this vary between staff	**Minor**

Standard	**Inspection findings**	**Level of shortfall**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of Practice		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.	During the traceability audit of PM blocks and slides kept in the mortuary, the inspection team identified a number of cases from 2020 that are still in storage. The establishment informed the inspection team that they are still waiting for communication from the Coroner however there has been no active follow-up.	**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.	GQ3 (a)	Porter training records are held by the Portering manager. The DI is advised to keep a list of porters that have completed mortuary training for auditing purposes.
2.	T1 (a)	During the body audit the inspection team found an error between the wrist and ankle band on one of the deceased. Mortuary staff are advised to review all body ID tags on admission to ensure information is correct and consistent.
3.	T1(c)	One body that was audited from the freezer had the wrist band facing the wrong way which made it difficult to check. The DI is advised to add to the long stay SOP that the ID bands are to be positioned in an easily viewable way prior to the freezing of bodies.
4.	PFE3 (a)	The DI is advised to monitor the condition of the PM room floor where it is starting to show signs of wear to ensure that the porous material underneath does not become exposed.
5.	PFE3(a)	The dissection boards within the PM room are starting to show signs of wear and the DI is advised to replace them.
6.	PFE3(c)	Although the ventilation system in the PM room is serviced annually it is only meeting the necessary requirements by a small margin. The DI is advised to seek guidance on this to ensure that it continues to meet the requirements.
7.	N/A	The DI is advised to do a gap analysis against the HTA standards for any unlicensed body stores that come under the Trust to identify areas of risk and determine follow up actions to mitigate these risks.

Commented [MW1]: Does this relate to one body?

Commented [JS2R1]: Yes. Will clarify this in the advice.

Background

Glangwili General Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most

recent previous inspection took place in July 2021.

Since the previous inspection, there has been a revocation of a satellite site in October 2023. This site is still under the same governance of the hospital trust. There has also been a recent change of Corporate Licence Holder contact (CLHc), Designated Individual (DI) and Persons Designated (PD) 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).

The inspection team also undertook advisory inspections of the unlicensed body stores at Prince Philip Hospital, Withybush General Hospital and Bronglais General Hospital. The unlicensed body stores are under the same staffing and governance structure as the hub site. The sites are not licensed as no licensable activity is undertaken. Only standards relating to body storage and conditions that may impact dignity of the deceased were assessed on an advisory basis. Accordingly, the advisory inspection focused on the following standards: GQ1(c), T1(a), T1(b), T1(c), T1(d), T1(e) T1(f), PFE1(a), PFE1(c), PFE1(d), PFE1(e), PFE2(a), PFE2(b), PFE2(c), PFE2(d), PFE2(e), PFE2(f), PFE2(g), PFE3(a), PFE3(b), PFE3(d) and PFE3(f).

Details of the advisory inspection findings can be found in appendix 3 of this report.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and PM room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, incidents and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises at the hub site and the unlicensed body store sites which included the mortuary body storage areas, the viewing rooms, and the PM room at the hub site. Also inspected was the storage area for tissue retained at post mortem examination at the hub site.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage at the hub site, three bodies at the unlicensed body store site at Prince Philip Hospital, three bodies at Withybush General Hospital and three bodies at Bronglais General Hospital. This included bodies with same/similar names and a body in frozen storage. Traceability details were crosschecked between the identification bands on the body, information on the mortuary whiteboard, associated records of the deceased and the mortuary register. A discrepancy was identified at the hub site where the year of birth on one of the ID tags was mixed up with the year of death (*see advice item 2*).

Audits were conducted of tissue and organs taken at PM examination for four cases at the hub site. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, records and the tissue blocks and slides being stored. No discrepancies with traceability were identified however a shortfall was identified in relation to the continued storage of blocks and slides (*see shortfalls against GQ2 (c) and T2 (b)*).

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence including members of mortuary, the mortuary manger, the regional mortuary manager, the portering manager, a porter, staff involved in the consent seeking process for PM examination, the quality manager, the DI and a pathologist undertaking PM examinations.

Report sent to DI for factual accuracy: 16 April 2024

Report returned from DI: 02 May 2024

Final report issued: 07 May 2024

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: 15 November 2024

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.

Appendix 3: Advisory inspection of the unlicensed body stores at Prince Philip Hospital, Withybush General Hospital and Bronglais General Hospital

Advice

The HTA advises the DI to consider the following to further improve practice at the unlicensed body stores:

Number	Standard	Advice – Prince Philip Hospital
1.	GQ2 (a)	Mortuary staff are unable to access CCTV recordings, and therefore mortuary access audits cannot be carried out against the CCTV to ensure adherence to relevant policies and procedures. The establishment is advised to request access to internal CCTV.
2.	PFE1(c)	Whilst the viewing room was clean at the time of the advisory inspection, there were ceiling tiles that showed signs of water damage and the area where viewings are conducted does not allow sufficient space for family members. The establishment is advised to repair the damaged ceiling tiles and consider renovating the viewing room.
3.	PFE1 (d)	There is CCTV outside the mortuary entrance, however there are some blind spots which block the view to some parts of the facility. The establishment is advised to have CCTV covering the entire storage facility.
4.	PFE1(e)	Mortuary management do not have direct control of granting and removing access to the mortuary on the swipe card system. This is controlled by a different department in the hospital. Whilst swipe card access lists are reviewed and updated by the regional mortuary manager, there is no assurance that security arrangements protect against unauthorised access and the establishment is advised to have full oversight of mortuary access control.
5.	PFE2 (a)	The establishment are advised to screen the funeral directors entrance at this site. This is to prevent oversight of activity in the body store as the rear body store doors open out directly into an area which is frequented by passing Health Board staff, the public and service workers. In addition, the

		establishment are advised to remove the damaged and decommissioned storage unit directly outside the mortuary.
6.	PFE2 (c)	The establishment is advised to address the ongoing issue of lack of freezer storage.
7.	PFE2 (e)	Mortuary staff are advised to regularly test and record fridge alarms to assure themselves that call out procedures are working effectively.
8.	PFE2 (f)	The establishment are advised to monitor the temperatures of the fridges to identify trends and any variations in storage temperatures.
9.	PFE3 (a)	The establishment is advised to review the areas in the mortuary that are difficult to adequately clean and disinfect due to being made of porous materials. These include, but are not limited to: • Wooden doors and work surfaces • Grouting on the mortuary floor

Number	Standard	Advice – Withybush General Hospital
1.	GQ2(a)	Mortuary staff are unable to access CCTV recordings, and therefore mortuary access audits cannot be carried out against the CCTV to ensure adherence to relevant policies and procedures. The establishment is advised to request access to internal CCTV.
2.	PFE1(a)	The mortuary facility was very warm with a lack of air conditioning. This may affect the efficiency of the body store fridges, and in particular the temporary unit, which then needs to work harder generating more heat. The establishment is advised to review and risk assess the arrangements to ensure that the premises remain fit for purpose.
3.	PFE1(a)	The establishment is advised to review the areas in the mortuary that are difficult to adequately clean and disinfect due to being made of porous materials. These include, but are not limited to: • Wooden doors and door frames (some of which are extensively chipped)

		• Chipped body store trays • Corroded racking within the fridges
4.	PFE1(a)	The racking within the fridges is corroded and rusted, including where it is bolted onto the floor. The establishment is advised to seek guidance and risk assess this to ensure that its integrity is not compromised and it remains fit for purpose.
5.	PFE1(a)	There are many roof tiles missing throughout the mortuary and body store areas which need to be replaced.
6.	PFE1(d)	There is CCTV in the mortuary, however there are some blind spots which block the view to some parts of the facility. The establishment is advised to have CCTV covering the entire storage facility.
7.	PFE1(e)	Mortuary management do not have direct control of granting and removing access to the mortuary on the swipe card system. This is controlled by a different department in the hospital. Whilst swipe card access lists are reviewed and updated by the regional mortuary manager, there is no assurance that security arrangements protect against unauthorised access and the establishment is advised to have full oversight of mortuary access control.
8.	PFE1(d)	The Funeral Directors entrance is secured by three manual locks and bolts that can be secured from the inside of the mortuary only. The manual nature of this increases the risks of human error leading to leaving the facility unsecured. The DI is advised to risk assess these security arrangements.
9.	PFE2(a)	The trolleys within the mortuary do not have an electronic roller system. In order to retrieve the bodies stored on the top trays of the units, two members of staff need to climb step ladders on each side of the trolley and manually pull out the tray. During the body audit, this procedure was observed and concerns were highlighted regarding both the safety of the mortuary staff and the dignity of the deceased. Due to capacity, the top shelf of the fridge is required to be used and so the establishment is advised to review the procedures and risk assess current practice in order to put mitigations in place which will allow staff to work safely and not compromise the safety of the deceased.

10.	PFE2(a)	During working hours mortuary staff are expected to collect the deceased from the wards. The mortuary is a busy department facilitating hospital and community admissions, releases, transfers, viewings and routine care of the deceased. The current arrangements means that important mortuary duties need to be delayed, or the deceased remains on the ward for extended periods of time. This poses a risk to the dignity of the deceased. The establishment are advised to change these arrangements in line with national practice and have portering staff collect deceased from wards both in and out of hours, allowing mortuary staff to fulfil mortuary duties.
11.	PFE2(b)	There is a number of fridge units that have been donated to the hospital to increase body store capacity. The units are not currently functional due to maintenance issues in the room. The establishment is advised to prioritise the work that is required to ensure that the units are commissioned and the much needed capacity is increased (which will also increase bariatric storage capacity).
12.	PFE2(c)	The establishment is advised to address the ongoing issue of lack of freezer storage.
13.	PFE2(e)	There is a temporary body store fridge (that is in continual use) within the main body store that does not have remote monitoring and alarm systems. This is not sufficient to alert staff in the event that the storage temperature deviates from an acceptable range.
14.	PFE3(f)	Although the fridges are subject to maintenance when required the establishment is advised to include these on servicing contracts as a preventative measure (as opposed to a responsive measure).

Number	**Standard**	**Advice – Bronglais General Hospital**
1.	GQ2(a)	Mortuary staff are unable to access CCTV recordings, and therefore mortuary access audits cannot be carried out against the CCTV to ensure adherence to relevant policies and procedures. The establishment is advised to request access to internal CCTV.
2.	PFE1(a)	The establishment is advised to review the areas in the mortuary that are difficult to adequately clean and disinfect due to being made of porous materials. These include, but are not limited to:

		• Wooden doors and door frames (some of which are extensively chipped) • Heavily rusted trolley • Rust on the fridge floors
3.	PFE1(a)	The seals on the fridge doors are mouldy and perishing. This may compromise the efficiency of the refrigeration. The establishment are advised to review the age of the fridges and determine whether the units themselves are fit for purpose, or whether necessary maintenance of the internal components is required.
4.	PFE1(d)	There is CCTV in the mortuary, however there are some blind spots which block the view to some parts of the facility. The establishment is advised to have CCTV covering the entire storage facility. There is no CCTV or camera on the mortuary entrance allowing the staff to identify who is visiting prior to opening the door. This poses a risk to staff who are often lone working.
5.	PFE1(e)	Mortuary management do not have direct control of granting and removing access to the mortuary on the swipe card system. This is controlled by a different department in the hospital. Whilst swipe card access lists are reviewed and updated by the regional mortuary manager, there is no assurance that security arrangements protect against unauthorised access and the establishment is advised to have full oversight of mortuary access control.
6.	PFE2(a)	The establishment are advised to screen the funeral directors entrance at this site. This is to prevent oversight of activity in the body store during releases. The double doors open out directly into a busy public area including the entrance to the Accident and Emergency department.
7.	PFE2(a)	During working hours mortuary staff are expected to collect the deceased from the wards. Lone working at this establishment is commonplace, with staff facilitating hospital admissions, releases, transfers, viewings and routine care of the deceased. The current arrangements means that important mortuary duties need to be delayed, or the deceased remains on the ward for extended periods of time. This poses a risk to the dignity of the deceased. The establishment are advised to change these arrangements in line with national practice and have portering staff collect deceased from wards both in and out of hours, allowing mortuary staff to fulfil mortuary duties.

8.	PFE2(b)	There are 20 refrigerated spaces to store the deceased, however there are only 16 usable due to the current trolley not being able to reach the top or bottom spaces. The establishment is advised to review these arrangements to determine if they are suitable.
9.	PFE2(c)	The establishment is advised to address the ongoing issue of lack of freezer storage.
10.	PFE3(f)	Although the fridges are subject to maintenance when required the establishment is advised to include these on servicing contracts as a preventative measure (as opposed to a responsive measure).