Inspection report on compliance with HTA licensing standards
Inspection date: **27-28 July 2021**

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*
Pathology lab			*Carried out*
Satellite site **Withybush General Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)			*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, 10 major and six minor shortfalls were found against standards for consent, 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
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 training for those seeking consent for adult hospital PM examinations.	**Major (Cumulative)**
b) Records demonstrate up-to-date staff training	No records were provided to demonstrate staff have up-to-date training. No accessible records are held for staff to determine who is appropriately trained to seek consent.	
d) Competency is assessed and maintained	Staff competency in seeking consent for adult PM examination is not assessed.	
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) lack sufficient detail such that whilst the key steps are included these do not specify all the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • admitting bodies to the mortuary; • release of bodies to funeral directors; • identification of deceased for viewing of bodies; and • transfer of deceased to other establishments. This is not an exhaustive list of the SOPs requiring amendments, and 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	The establishment does not have a procedure in place for checking and documenting the condition of bodies following receipt in the mortuary.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records, and traceability of bodies and samples.	**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	There is no system in place for training portering staff undertaking their duties within in the mortuary.	**Major**
c) Staff are assessed as competent for the tasks they perform	Although staff are ‘signed off’ on completion of training, there is no programme of on-going competency assessment.	**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	There is no assurance that undertaking licensable activities know how to identify and report HTA Reportable Incidents (HTARIs).	**Major (Cumulative)**
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed	The establishment does not have a documented process for identifying and reporting potential HTA Reportable Incidents incident reporting system in place for all areas under the licence. Therefore the DI cannot be assured that staff are aware and know how to report incidents. The DI cannot be assured that when incidents occur, follow-up actions are completed. Records of incidents do not document sufficient details of incident findings and follow-up actions.	
d) Information about incidents is shared with all staff to avoid repeat errors	There is no mechanism or practice of sharing information about incidents with the portering and maternity teams.	
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	Procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • Identification of bodies for release from the mortuary to funeral directors may be performed using the green form provided by the funeral directors; and • Identification of bodies for viewings may be based on only two identifiers of the deceased provided by the family upon arrival at the mortuary.	**Major**
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	There is no documented procedure in place for the transportation of toxicology samples to another establishment for analysis.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment cannot provide evidence that the ventilation system in the PM room has been serviced regularly. The last available report was from 2019.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The policy for seeking consent references previous versions of the HTA's Codes of Practice and references 'Next of Kin'.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP for seeking consent references 'Next of Kin'.	**Minor**
f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	The documentation for taking consent for paediatric/perinatal and adult hospital post mortem examination does not include the timeframe in which they are able to change their mind.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Many of the establishments SOPs have the same author and authoriser.	**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	The temperature alarm trigger points for the fridges and freezers are not set at appropriate temperatures to ensure that the alarms will trigger when storage temperatures deviate from acceptable ranges.	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis	The establishment does not have a formal system to monitor, review and record trends in storage temperatures.	**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.	T1d	The DI is advised to be assured that porters are aware of the similar name procedure.
2.	PFE2b	As part of the response to the COVID pandemic the establishment have implemented a process for monitoring mortuary capacity in order to highlight potential issues before they arise. The DI is advised to consider making this process a routine procedure to monitor capacity in the future.

3.	PFE2c	The DI is advised to ensure that contingency arrangements are in place in the event a bariatric body requires transfer to a freezer.

Background

Glangwili General Hospital (GGH) 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.

GGH has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2016.

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

Standards T1f were not assessed as they are not applicable to the activities undertaken. Standards GQ3d, GQ3e, GQ3f, GQ3g, GQ4b, T1b, PFE1a, PFE1b, PFE1c, PFE2d, PFE3b, PFE3d and PFE3e are applicable but were not assessed as this was a virtual regulatory assessment. The remaining 58 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, records of equipment servicing, audits, risk assessments, meeting minutes and reported incidents.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, acting Mortuary Manager, a Pathologist, portering staff and maternity consent seeker representative.

Report sent to DI for factual accuracy: 10 August 2021

Report returned from DI: 17 August 2021

Final report issued: 20 August 2021

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 Virtual Regulatory Assessment Report.

Date: 20 December 2021

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.