Inspection report on compliance with HTA licensing standards
Inspection date: **07 & 08 November 2023**

University Hospital of Wales
HTA licensing number 12163

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 **University Hospital of Wales**	Licensed/	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 University Hospital of Wales ('the establishment') had met the majority of the HTA's standards, one major shortfall was found against standards for premises, facilities and equipment. This related to two body storage units not being connected to an alarm system at the time of the inspection.

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 shortfall identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
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	A temporary refrigerated unit used for storage of bodies during predicted peaks of activity in the mortuary and a fridge unit in the fetal pathology department were not connected to an alarm system at the time of the inspection. This means that staff would not be alerted to temperature deviations in a timeframe that could prevent the risk of deterioration to the deceased.	**Major**

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.	C1(c)	The DI is advised to consider how the information leaflets for those giving consent for post mortem examination are version numbered. Whilst the leaflets contain all relevant information and have been subject to regular review, the date on the leaflets is listed as 2010. This infers this leaflet may not be the most current version.
2.	GQ1(c)	Whilst the establishment have a procedure in place to regularly monitor the condition of the deceased, the DI is advised to include an agreement of the condition of the body with funeral directors upon release. This will ensure that the final condition of the body prior to release is recorded should there be any concerns raised at a later date. Furthermore, the DI is advised to detail in the condition monitoring SOP the actual frequency of the condition checks undertaken.
3.	GQ2(a)	Whilst the establishment are undertaking quarterly security access audits which reviews the CCTV access to visitor logs and swipe card access, the DI may wish to consider reviewing the CCTV more frequently as data on this system is only captured for a period of 31 days.
4.	GQ3(a)	Training was provided to porters on mortuary security measures and expected behaviour in the mortuary however, this is not fully recorded in the porter training document. The DI is advised to update the training document to fully reflect the training that has been provided to portering staff.
5.	T1(a)	The DI is advised to liaise with local police forces to improve the system for the labelling of bodies at the place of death prior to admission to the mortuary. This may ensure the number and types of identifiers used on identification bands is consistent.
6.	T1(b)	The mortuary is heavily reliant on paper-based tracking systems for the deceased. The DI is advised to consider an electronic mortuary tracking system so staff are able to manage traceability of the deceased and their associated records more effectively.

7.	PFE1(a)	Very occasionally relatives of the deceased may accompany the body part way to the mortuary with the porters and nursing staff. The DI is advised to review the route that may be taken and ensure that the route is sensitive to the experience of families.
8.	PFE1(e)	The doors between the body storage area and the viewing rooms are secured using a manual lock. The DI may wish to consider steps to mitigate the risk of unauthorised access to the body store and the stored consumables area should manual locks not be deployed. The DI is further advised to consider the type of mortuary consumables that are stored in this area to minimise any risks should visitors accidentally enter this area.
9.	N/A	The establishment have recently been allocated funding to fully refurbish the mortuary. The DI is advised to review the following document as part of this refurbishment plan: NHS England » Health Building Note 16-01: Facilities for mortuaries, including body stores and post-mortem services which may be helpful.

Background

University Hospital of Wales has been licensed by the HTA since July 2007. This was the third routine inspection of the establishment; the most recent previous routine inspection took place in August 2017. Following this inspection, the establishment were subject to two further follow up CAPA inspections held in September 2017 and November 2018.

Since the previous routine inspection, a change to the role of DI occurred in September 2017, and a further change occurred in June 2019 to the current DI. Changes to the role of CLHc occurred in April 2019 and September 2019 with the current CLHc being in the role since October 2021. Changes to the roles of Persons Designated occurred in October 2018, September 2019, and January 2023.

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 of the hub site (standards published 3 April 2017).

The inspection team also undertook an advisory inspection of the unlicensed body store at University Hospital of Llangdough which is used by the establishment as part of contingency storage arrangements. The unlicensed body store is under the same staffing and governance structure as the hub site. This site is 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, body and tissue traceability audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported 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 site which included the mortuary body storage areas, the PM room at the hub site, the viewing rooms, the neuropathology laboratory, and the fetal pathology laboratory 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 both the hub and unlicensed body store site. This included bodies with same / similar names, a perinatal body, 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, the mortuary electronic database and the mortuary register. No discrepancies with traceability were identified.

Audits were conducted of tissue and organs taken at PM examination for seven cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, the laboratory tissue spreadsheet and the wet tissue, organs, tissue blocks and slides being stored. Five cases were identified as being stored for a scheduled purpose with appropriate consent. One case had been disposed of in line with the wishes of the family. One case was still ongoing with the Coroner and the tissue had been segregated into a different area of the storage room as the wishes of the family were for this to be returned to them at a later date. No discrepancies with traceability were identified.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence including members of mortuary staff, the mortuary manger, a member of the portering staff, staff involved in the consent seeking process for perinatal and adult PM examination, a pathologist who undertakes PM examination, pathology staff, the quality and training managers, and the DI.

Report sent to DI for factual accuracy: 30 November 2023

Report returned from DI: 11 December 2023

Final report issued: 13 December 2023

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: 26 February 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 store at University Hospital of Llangdough

Advice

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

Number	Standard	Advice
1.	GQ4(a)	Whilst this standard was not covered during the advisory inspection, the inspection team identified a large volume of historic paper mortuary records stored within a cupboard at this site. The establishment are advised to review the records and determine if continued storage is relevant. Where it is determined that records are required for continued storage, the establishment may wish to consider backing these records up electronically.
2.	PFE1(d)	Whilst the condenser units for the refrigerated body storage areas were mounted quite high on the wall to the exterior of the mortuary, the establishment are advised to check that the control switches cannot be accessed or tampered with.
3.	PFE1(e)	Whilst the mortuary at the unlicensed body store appeared secure at the time of the inspection and there are regular security audits of access undertaken, the establishment is advised to expedite plans in place to replace external door key locks with swipe card access to mitigate risk of unauthorised access should manual locks not be deployed. Whilst the establishment are undertaking quarterly security access audits of this site also, which reviews the CCTV access to visitor logs, the establishment may wish to consider reviewing the CCTV more frequently as data on this system is only captured for a period of 31 days.
4.	PFE2(e)	The establishment are advised to test the body storage alarm system on a regular basis and to include testing of the alarm system out of hours to ensure there is response to alarms as expected.
5.	PFE2(f)	The establishment is advised to expedite the plans in place to have the body storage units on a remote temperature monitoring system. Currently the storage units are not monitored over weekends and bank holiday periods. This poses a risk to deviations in temperatures not being identified in a timeframe which could prevent the onset of deterioration to the deceased.