Inspection report on compliance with HTA licensing standards
Inspection date: **16 July 2024**

Blackpool Victoria Hospital
HTA licensing number 30031

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 **Blackpool Victoria Hospital**	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 Blackpool Victoria Hospital ('the establishment') had met the majority of the HTA's standards, four major and nine 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
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.	Not all relevant Standard Operating Procedures (SOPs) consistently refer to checking three points of identification at different stages of a procedure. SOPs should include what the identifiers could be and what they are checked against. Examples include but not limited to: • CPP MORT 039 Tranfer of patients off site for CTPM examination of independent PM. • CPP MORT 006 Post mortem examination procedure (including the identifiers for specimens). SOP CPP MORT 018 Visiting a deceased is not clear that a viewing form is used to check three identifiers of the deceased with the relatives and on the body before a viewing proceeds. In addition, the process for viewings out of hours conducted by portering staff contains insufficient detail *(see shortfall against T1(c))*. SOP CPP MORT 010 Release of a body to a funeral director refers to the 'Notice of Infection' form given to funeral directors which can include the type of infection a body may have, not just the route of transmission. The information provided should be limited to whether the deceased could be infectious and the potential route of transmission to enable funeral directors to manage the deceased safely. In addition, it is not clear that where a release form may need to be completed by a funeral director at the mortuary, the identifiers of the deceased should not be provided from mortuary documentation, as this presents a risk of releasing a wrong body. SOP CPP MORT 043 Mortuary security and the MORT/POL/003 Mortuary security policy do not contain all security information or measures relating to the mortuary. For example: • The security of the external body storage unit, the area where the unit is located or how access to this area is managed.	**Major**

	• The use of visitor logs to maintain accurate records of those persons who do not have swipe access is not included in the policy. • The use of keys and how these are accessed and managed. *See advice item 4*	
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	The process for viewings out of hours is not robust; • bodies are prepared using two identifiers of the deceased (name and date of death); • ward staff check the identification of the deceased prior to the relatives viewing but there is no detail of what they are checking the details against; and • it is not clear if the the identification details of the deceased are checked with the relatives, or just the accompanying nursing staff. The current process presents a risk of viewing a wrong body. The inspection team identified three discrepancies for one body with a same/similar name during the body audit: • the name was spelt differently between the identification bands and the mortuary paperwork; • there was a discrepancy in the address details between both identification bands on the body and the mortuary paperwork; and • the body did not have the mortuary register number stickers on the identification band or the identification card on the body, as per the SOP.	**Major**
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	The current standard of cleaning and disinfection of the post mortem (PM) rooms is inadequate. The inspection team identified the following areas within the PM rooms that require attention: • One dissection bench sink plug hole was contaminated with debris. • The floor drains in the main PM room contained hair, debris and flies. • Blood was seen on the side of the clinical waste bin, at the base of one PM table and on the instrument trolley sheet in the high-risk PM room. • The sponges on the dissection units were not clean. In addition, the edge of the flooring between the floor and wall near two of the PM dissection units is split, which will allow ingress of water and other contaminants. *See advice item 8*	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment currently undertake a six monthly security audit of CCTV, swipe card access and visitor logs. However, mortuary CCTV footage is erased every 28 days meaning the audit does not include review of CCTV footage for the entire period. In addition, the current audit frequency may not ensure issues or incidents are followed up in a timely manner. *See advice item 10*	**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		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The post mortem (PM) consent form used to document relatives wishes for adult cases does not reflect the options for organs and tissue outlined in the adult PM consent policy. The form does not give the option of reuniting organs or tissue and slides with the body following examination. In addition, the options relatives can consent to for the use of tissue blocks and slides are given as one option, meaning relatives would have to consent to all uses when perhaps they would only wish to consent to one. The options of medical research and education for tissue blocks and slides is included twice. The options for tissue blocks and slides are also given as one option for paediatric/perinatal cases. *See advice item 2* *The establishment submitted evidence to partially address this shortfall before the report was finalised.*	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
e) There is a system for recording that staff have read and understood the latest versions of these documents	Not all mortuary staff have read and acknowledged SOPs that govern their work. Where staff have read and acknowledged SOPs, this has not always happened in a timely manner.	**Minor**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	The frequency and number of cases included in audits is not sufficient to provide assurance of mortuary activities. For example, the receipt of a body audit conducted in April 2023 included five bodies and identified four non-conformances. This audit is not due to be repeated until April 2025.	**Minor**
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 training records for porters who conduct viewings out of hours does not include the requirement to check a minimum of three identifers of the deceased when preparing or conducting a viewing. Some of the training records for funeral directors who admit bodies out of hours only, show they have been signed off to conduct viewings out of hours, which is incorrect. Some records are not fully completed which does not provide assurance that staff are fully trained.	**Minor**
c) Staff are assessed as competent for the tasks they perform	The competency records provided during the inspection for a qualified Anatomical Pathology Technologist (APT) did not include a competency assessment for evisceration and reconstruction of bodies.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The record of the number and types of tissue retained at PM examination for histological examination is not kept by the mortuary or written on the histology specimen card sent to the laboratory with the tissue. Therefore, laboratory staff are unable to confirm if the tissue they receive in the laboratory for processing is correct.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
g) Bodies are shrouded or in body bags whilst in storage	Not all bodies in storage were fully covered and the inspection team identified some bodies wrapped in sheets that were soiled to a minor degree.	**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	The trolley used to transfer bodies to and from funeral director vehicles is damaged. Some of the metal frame has come off and the porous wood underneath is exposed. There is a risk of accidental damage to a body and the equipment cannot be adequately cleaned or disinfected.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Although the establishment have tested the ventilation system, it is not clear from the report if the ventilation for the isolation PM room is operating correctly.	**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.	C1(c)	The DI is advised to remove references to 'next of kin' when the PM information booklet for relatives is next reviewed.
2.	C1(g)	The DI is advised to adopt the the HTA model PM consent form for adult cases and the Stillbirth and neonatal death (Sands) charity model PM consent forms. Both are available via the HTA website.
3.	C2(b)	The DI is advised to ensure that training and competency is regularly refreshed for adult and perinatal PM consent seeking and documented records are maintained.

4.	GQ1(a)	The mortuary manager is advised to: • record the final condition check of bodies when they are released into the care of a funeral director; and • include the procedure for testing and recording the fridge and freezer alarms and ensure the correct alarm trigger points are referenced in the relevant SOP. In relation to security procedures the DI is advised to: • Consider the benefit of having a mortuary security policy and SOP with similar information; • detail the frequency of how often mortuary security audits will be conducted and the mortuary swipe card access list will be reviewed; and • ensure the review of mortuary visitor logs is included.
5.	GQ1(h)	The DI is advised to formalise and document regular meetings with all PDs overseeing activities covered by the licence.
6.	GQ6(a)	The mortuary manager is advised to: • include the risk of accidental damage to bodies in the PM risk assessment; • assess the risk to staff not being able to to visually verify who is requesting access to the mortuary corridor area, or the external area at the back door of the mortuary; • include staff training and competency as an existing control measure in relevant risk assessments when they are next reviewed; and • remove any out of date information/practices referenced in risk assessments.
7.	GQ6(b)	The mortuary manager is advised to consider ways for staff to demonstrate they have read and acknowledged risk assessments relevant to their work, now that they are held centrally by the Trust and not routinely distributed to them via the quality management system.
8.	PFE1(a)	The mortuary manager is advised to:

		• implement a more thorough cleaning schedule for the PM rooms and undertake regular cleaning audits to help ensure cleaning standards are maintained; • ensure the UV insect light in the PM room is repaired as soon as possible and consider installing additional ones in the PM rooms; and • investigate the cause of the patchy staining on the PM room floor and explore options to address this.
9.	PFE1(d)	The DI is advised to ensure the CCTV camera covering the area where the external body store is located is functional and that footage can be accessed and reviewed should the unit be required for use in the future.
10.	PFE1(e)	To increase security measures, the DI is advised to: • continue with the plans to implement new internal CCTV in the mortuary which can be accessed and regularly reviewed by mortuary staff as part of ongoing mortuary security audits; • increase the frequency of the security audits to ensure timely follow-up of any issues that may be identified; • include follow-up of any failed or unusual access attempts in to the mortuary identified in security audits; • check the mortuary doors after electrical generator tests or any power failure to ensure they have automatically closed and the magnetic door locks have re-engaged. This should also be included in the relevant SOP; and • change any key/alarm pad codes regularly.
11.	PFE2(a)	In relation to the static collection of potted historical specimens, the DI is advised to consider if it is still appropriate to continue storing these specimens as they are no longer accessed for teaching purposes and require some maintenance to ensure they continue to be preserved/stored in a dignified manner.

Background
Blackpool Victoria Hospital has been licensed by the HTA since October 2010. This is the fifth inspection fo the establishment: the most recent previous inspection took place in January 2022

Since the previous inspection, there has been a change of Corporate Licence Holder contact (CLHc) in May 2024.

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 team reviewed the establishment's self-assessment document provided by the DI and mortuary manager in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuaries were reviewed. This included SOPs, risk assessments, audits, incidents, meeting minutes training records and competency assessment documents. Consent seeking procedures and information for families giving consent for adult and perinatal PM examinations were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas (including the external fridge unit), viewing rooms and PM rooms. Storage arrangements for relevant material held within the pathology department was also reviewed, including a static collection of potted historical specimens which is documented and reviewed *(see advice item 11).*

Audit of records
The inspection team undertook audits of traceability for four bodies in storage. This included a perinatal case, bodies with same/similar names and a body in long term storage. Traceability details were crosschecked between the identification bands on

the bodies, information in the mortuary register, paperwork and mortuary electronic record. Three discrepancies were identified in one case with a same/similar name *(see shortfall against T1(c)).*

Audits were conducted of stored tissue taken at PM examination for three cases; two coroners cases and one hospital consented case. Information was crosschecked between the mortuary documentation, mortuary tissue spreadsheet, Coroner's paperwork/ family wishes forms, hospital post mortem consent form and tissue being stored. No discrepancies were identified.

The assessment team also observed the release of three bodies to a funeral director. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including mortuary staff, histopathology staff, a quality manager, a portering staff member, a pathologist (the DI) and staff involved in the consent seeking process for adult and perinatal PM examinations.

Report sent to DI for factual accuracy: 8 August 2024

Report returned from DI: 16 August 2024

Final report issued: 16 September 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: 20 January 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.