Inspection report on compliance with HTA licensing standards
Inspection dates: **24 and 26 January 2022**

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, two major and four minor shortfalls were found against standards for Consent, Governance and quality systems 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

Standards	**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 formalised process for the consent training of clinicians who seek consent for adult (hospital) PM examinations. The Trust issue a consent seeking policy that outlines the PM consent seeking process however it is not sufficiently detailed to cover all the requirements of the HT Act.	**Major (cumulative)**
b) Records demonstrate up-to-date training	There are no accessible records held by the DI to determine who is appropriately trained to seek consent for adult (hospital) PM examinations. Staff self-certify that they have read relevant consent documentation.	
d) Competency is assessed and maintained	Staff competency in seeking consent for adult PM examination is not assessed.	

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 frozen storage capacity for the long-term storage of bodies.	**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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	There is no documented SOP detailing the consenting process for adult and paediatric PMs	**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	It is not clear within the written information provided to families how consent can be withdrawn including who to contact and the timeframes in which they are able to change their minds.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.	There is a static collection of potted historical specimens within the histology laboratory which have not been incorporated within the establishment's governance framework.	**Minor**

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 ventilation system within the post mortem room does not provide the necessary ten air changes per hour.	**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.

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

Number	Standard	Advice
1.	C1(a)	The DI is advised to review the Trusts *'Consent for Examination or Treatment Policy (CORP/PROC/102)'* for references to previous versions of HTA Codes of Practice.
2.	C1(c)	The DI is advised to review the following documents to remove references to Next of Kin- • *A Guide to the Post Mortem examination procedure (adult) (CPP MORT 002)* • *A Guide to the Post Mortem examination procedure (baby or child) (CPP MORT 002)* • *CPP MORT 002: Receipt of a Body following a Death in the Hospital (CPP MORT 001)* • *CPP Mort 006: Post Mortem Examination Procedure (CPP MORT 006)*
3.	C1(g)	The patient information booklet for post mortem examination is named differently to that referenced on the PM consent form. The DI is advised to update this reference.

4.	GQ1(a)	During a PM procedure three points of identification on the deceased are checked with paperwork prior to commencement. The DI is advised to detail what specific points of ID are checked within the SOP for clarity and consistency.
5.	GQ6(b)	The establishment has a comprehensive suite of risk assessments however the DI is advised to review the risk assessment *'928: Conducting a PM'* to ensure that all risks relating to this procedure have been covered including HTA reportable incidents such as PM being carried out with inadequate consent and PM on the incorrect body.
6.	T1(b)	There are two mortuary registers that are completed to track each body from admission to release. Although the audits showed full traceability, some sections of the mortuary registers were incomplete. The DI is advised to regularly audit the register for completeness.
7.	T1(d)	The DI is advised to detail the procedure for identifying bodies with the same or similar name within the following documents- • *Receipt of a Body Following a Death in the Community (PP MORT001)* • *Receipt of a Body following a Death in the Hospital (CPP MORT 002)*
8.	PFE1(c)	The PM room is clean however the DI is advised to check that the cleaning schedule for the drains within the PM room is adhered to and is being completed weekly.
9.	PFE2(a)	Although condition checks are carried out routinely for all bodies, the DI is advised to formalise the checks and document the findings.
10.	PFE3(a)	The dissection boards within the PM room are starting to show signs of wear and the DI is advised to replace them.
11.	PFE3(b)	There is a small trolley that is used to assist funeral directors in the transfer of the deceased from the mortuary fridge tray onto the stretcher. The DI is advised to find a more robust replacement to reduce the risk of instability during the procedure.

Background

Blackpool Victoria Hospital has been licensed by the HTA since October 2010. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2016.

Since the previous inspection, there has been some significant changes to the licence arrangements including additional storage capacity being installed in 2020 and a change to the Corporate Licence Holder contact (CLHc) in 2021.

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 were reviewed. This included standard operating procedures, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage facilities, reported incidents, and training documents. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary, body storage areas, PM rooms and viewing rooms. Storage arrangements for relevant material held within the pathology department was also visited.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage. This included a perinatal case, bodies with same / similar name and a body in long term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and paperwork. All bodies were fully traceable. Some bodies were being stored beyond 30 days in the refrigerated storage units as the establishment does not have freezer capacity.

Audits were conducted of tissue taken at PM examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and tissue blocks and slides being stored. Full traceability of tissues was demonstrated for all three cases.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including mortuary staff, a pathologist who conducts PM examinations, a portering staff member, cell pathology manager, pathology quality manager, staff involved in the consent seeking process and the DI.

Report sent to DI for factual accuracy: 10 February 2022

Report returned from DI: No response

Final report issued: 25 February 2022

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: 30 November 2022

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.