Inspection report on compliance with HTA licensing standards
Inspection date: **10 January 2024**

Peterborough City Hospital

HTA licensing number 30032

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 **Peterborough City Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*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 Peterborough City Hospital ('the establishment') had met the majority of the HTA's standards, two major and one minor shortfall was found against standards for procedures on body storage, security of premises, and risk assessments.

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		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Procedures to monitor the condition of bodies are not conducted within a sufficient time period for mortuary staff to have oversight of any deterioration, and take appropriate action, as required. The inspection team noted that condition checks were not taking place on admission or release, and documented procedures stated that the first check would be on day twenty-one. Further, during an assessment audit, one body was found to have been in refrigerator storage for eight weeks, with signs of deterioration, without any documented condition checks. This is contrary to documented procedures and further increases the risk of deterioration without oversight.	**Major**
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 storage area(s) and PM room and the use of CCTV to monitor access)	Whilst individually locked and under CCTV surveillance, three external body storage units have been erected, and used, in an unsecure area of the mortuary grounds. The inspection team identified the following: • One external gate leading from the hospital grounds to the external fridge units was insecure and did not fully close. • One doorway next to the external shutters was unlocked and led to the external units. The inspection team were informed that this was required to allow members of the estates team to access control panels in that area. Further a fire exit leading to the mortuary service corridor was insecure and accessible from the outside. Whilst this is not a restricted part of the mortuary, this, and the absence of CCTV in the area, increases the risk of unauthorised access.	**Major (Cumulative)**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Visitors are not required to sign in and out of the mortuary. This further poses a risk to unauthorised access to restricted areas without oversight of mortuary staff.	**Major (Cumulative)**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	All procedures are risk assessed, but do not always contain individual key risks. Examples include: • All areas of access to the mortuary fridge areas. • Trolleys not reaching higher/lower tiers of the fridge, and the mitigation to use different trolleys as required. • Use, access to, and location of the temporary refrigeration unit. Further, the inspection team identified mitigations, such as same/similar name magnets and 'Tissue retained' wristbands documented in risk assessments but not being used.	**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(a)	The DI is advised to cross reference the intranet information regarding post mortem consent within the Trust's overall consent policy.
2.	GQ2(b)	The DI and mortuary manager are advised to review the template for internal audits to ensure that the person responsible, and timeframe for completion of actions, is clear.
3.	T1(c)	The mortuary manger is advised to record who has taken responsibility for checking identification during the viewing process to strengthen traceability.

4.	PFE1(a)	The DI is advised to monitor perished floor seals to the flooring within the post mortem room. Further deterioration may result in a shortfall to standard PFE1(a).
5.	PFE2(e)	The DI and maternity team are advised to include the process of escalation as part of their fridge alarm testing schedule.
6.	PFE3(a)	The DI is advised to monitor and address minor rust starting to form on the mortuary trolleys as further deterioration may compromise efficient decontamination and result in a shortfall to standard PFE3(a).

Background

Peterborough City Hospital has been licensed by the HTA since 15 November 2011. This was the fifth inspection of the establishment; the most recent previous inspection took place in October 2021.

Since the previous inspection, there has been a change to the designated individual in December 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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection

The inspection included a visual assessment of the mortuary access points, mortuary fridge room, post mortem room, tissue storage areas, maternity storage areas and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Audits were conducted for four bodies from refrigerated storage and one from frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified. However, condition checks, the use of same/similar name magnets or 'tissue retained' wristbands were not observed, this was contrary to the mortuary's documented procedures. *See shortfalls GQ1(c) and GQ6(a).*

Audits of traceability were conducted for tissue blocks and slides from four coronial cases. These included audits of the consent documentation for the retention or disposal of these tissues. No discrepancies were identified.

Meetings with establishment staff

Staff conducting processes under the licence were interviewed including the DI, mortuary manager, deputy mortuary manager, Pathology lead, Mortuary Porter, Pathologist, and Bereavement Midwife.

Feedback was provided on 10 January 2024 to the Designated Individual, Mortuary Team, Pathology Services Manager, Divisional Director, Cellular Pathology Manager Divisional Nursing Director, and Chief Executive.

Report sent to DI for factual accuracy: 07 February 2024

Report returned from DI: 20 February 2024

Final report issued: 23 February 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 April 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.