Inspection report on compliance with HTA licensing standards
Inspection date: **19 and 21 October 2021**

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*
A&E	-	*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 seven minor shortfalls were found against standards for Governance and quality systems, Traceability, and Premises, facilities and equipment. These related to standard operating procedures and risk assessments, traceability of tissues and organs sent offsite and security of the premises.

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
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Following a review of the establishment's incident log, the inspection team were not assured that out-of-hours security arrangements routinely protect against the risk of unauthorised access to the mortuary and that oversight of visitors with a legitimate right of access is maintained. Incidents relating to security of the mortuary included: • Access doors to the mortuary lobby being damaged or left ajar by the portering team leaving the lobby entrance to the mortuary unsecure. • An incident in which Funeral Directors admitting bodies out-of-hours did not have continual oversight by porters, in contravention of the mortuary's internal procedure.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
f) Temperatures of fridges and freezers are monitored on a regular basis	The refrigerated unit in the mortuary used for the storage of pregnancy remains is not subject to regular temperature monitoring. Furthermore, the unit is not connected to a remote alarm monitoring system.	**Major**

Minor 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.	Standard Operating Procedures (SOPs) do not always reflect current practice or do not include sufficient detail of identification checks performed relating to traceability of bodies, organs, and tissues. These include but are not limited to: • SOP CP-M-012 Visiting Deceased Patients - the inspection team noted that the staff carried out sufficiently detailed checks to identify the deceased against information provided by visitors, however this is not reflected in the SOP. • SOP CP-A-008 PM Tissue Retention & Disposal does not detail identification checks performed in the laboratory to ensure correct tissue has been prepared for disposal where this has been requested by the family. • SOP CP-M-031 Specimen Audit Trail does not sufficiently detail the process or identification checks performed prior to tissue or organs being returned to the body. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies, organs and tissues to ensure they contain sufficient details of identification checks performed and are reflective of current practice.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	The induction provided to visiting pathologists did not include appropriate training or awareness of the establishment's policies and procedures.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	There is no documented procedure detailing how errors in written records should be managed. The inspection team identified errors in mortuary written records which were illegible as a result of being overwritten.	**Minor**
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	Review of the incident log discovered that whilst staff know how to identify and report incidents, some incidents falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA as the establishment had determined them to be a near miss. *The establishment reported the incidents to the HTA following the inspection for review.*	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Risk assessments do not sufficiently detail how identified risks are mitigated. Furthermore, not all risk assessments have been reviewed against the HTARI categories to ensure there is mitigation for identified risks.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	The documented procedures for transfer of tissues and organs off site do not sufficiently detail the process that should be followed to confirm receipt of an organ or tissue.	**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 in the post mortem (PM) examination room maintains positive pressure. This may pose a health and safety risk to staff; however, this is currently being mitigated by staff using individual respirator systems.	**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 HTA website links and references to the HTA Codes of Practice in consent seeking policies to ensure they are up to date.
2.	C1(b)	The DI is advised to ensure that consent seeking SOPs and policies accurately reflect the withdrawal of consent procedure in place.
3.	C2(a)	The DI is advised to ensure that new doctors starting a rotation in the maternity department are informed of the requirement for the Trust consent seeking training to be undertaken and completed before seeking consent for PM examination.
4.	GQ2(a)	Regular audits of traceability of bodies in the mortuary are undertaken, however, many are performed retrospectively following release of bodies. The DI is advised to ensure audits routinely include a representative number of bodies actually in storage at the time of the audit.
5.	GQ5(a)	The DI is advised to review the HTARI reporting SOP, ensuring that all staff are aware of how to identify incidents which must be reported to the HTA including near-miss incidents.
6.	T2(b)	Whilst the audit conducted on traceability of tissue in the laboratory demonstrated full traceability of tissue, the inspection team identified a discrepancy in the information received form the Coroner's office. The DI is advised to schedule audits of information received from the Coroner's office to ensure discrepancies in information are identified and managed appropriately.
7.	PFE1(d)	Prior to the inspection, the establishment reviewed swipe card access to the mortuary lobby. Beyond the lobby, there are further security doors with key coded access locks, to which the swipe cards do not give access. The review identified that swipe card access to the mortuary lobby areas had not been limited to those with a legitimate right of access. Whilst the HTA were assured this had been rectified by the time of

		the inspection, the DI is advised to ensure regular review of swipe card access is undertaken. Furthermore, the DI is advised to implement a system to change codes to key coded locks used in the mortuary at regular intervals.
8.	PFE1(e)	The doors between the body storage area and the viewing rooms are secured using a manual lock. The DI is advised to review this security arrangement as the viewing rooms are directly accessed from the bereavement centre adjacent to the mortuary. The DI may wish to consider steps to mitigate the risk of unauthorised access to the body store should manual locks not be deployed.
9.	PFE2(e)	Whilst fridge alarm tests are undertaken, the DI is advised to implement regular unannounced fridge alarm tests for both the mortuary and maternity units. This will provide robust challenge of procedures that are in place to respond to alarms, to ensure they work as expected in the event of a unit failure.

Background

Peterborough City 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 2017.

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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The inspection team reviewed the establishments 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 post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records. 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 area, PM room and viewing room. The area within the maternity department for the storage of bodies was inspected as well as the storage arrangements for relevant material held within the pathology department.

Audit of records
The inspection team undertook audits of traceability for three bodies in storage. This included 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. No discrepancies were identified.

The inspection team also witnessed a release of a body from the mortuary and the preparation of a body for a viewing. Records produced and used to identify the bodies prior to the activities being undertaken were reviewed. The activities were conducted using three-points of identification of the deceased crosschecked between paperwork produced and the identification bands on the body. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, laboratory database, and tissue blocks, and slides being stored. Two cases reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. Full traceability of tissues was demonstrated for all four cases; however, a discrepancy was found with the Coroner's paperwork which recorded an inaccurate number of blocks having been taken compared to the number provided by the laboratory.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary staff, a pathologist who conducts PM examinations, a portering staff member, staff involved in the consent seeking process, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 29 November 2021

Report returned from DI: 08 December 2021

Final report issued: 20 December 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 Inspection Report.

Date: 21 May 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.