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

Luton and Dunstable University Hospital

HTA licensing number 12348

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 **Luton and Dunstable University 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 Luton and Dunstable University Hospital ('the establishment') had met the majority of the HTA's standards, three cumulative critical and one critical, 12 major and two 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

Critical 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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	There is no consent policy for perinatal post mortem (PM) examination reflecting the requirements of the HT Act 2004 and the HTA's codes of practice. *This shortfall was identified at the previous inspection in 2021.*	**Cumulative critical**
b) There is a documented standard operating procedure (SOP) detailing the consent process	There are no documented standard operating procedures (SOPs) which detail the process for seeking consent for perinatal PM examinations. *This shortfall was identified at the previous inspection in 2021.*	
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	Not all staff involved in the consent seeking process have received training which addresses the requirements of the HT Act and the HTA's codes of practice. *This shortfall was identified at the previous inspection in 2021.*	

b) Records demonstrate up-to-date staff training	The establishment does not have a process to identify which staff have received consent training and when refresher training is due. *This shortfall was identified at the previous inspection in 2021.*	**Cumulative critical**
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The establishment do not have a procedure to make it clear that if untrained staff are involved in seeking consent for PM examination, they should be accompanied by a trained individual. *This shortfall was identified at the previous inspection in 2021.*	
d) Competency is assessed and maintained	Competency in seeking consent has not been assessed and maintained. *This shortfall was identified at the previous inspection in 2021.*	
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.	The establishment's current SOPs are not fit for purpose and do not reflect current practice. An action plan is in place to create cross site procedures; however no significant progress has been made. *See shortfall against standard GQ6(c) for further detail.* *This shortfall was identified at the previous inspection in 2021.*	**Critical**
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The establishment cannot provide assurance that tissue is being disposed of as soon as reasonably possible. The establishment is currently storing tissue at a third party storage facility, and there are no regular audits conducted of all tissue stored to ensure staff are aware of what is held and why. *Refer to shortfall against standards T2 (a) for further detail*.	
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The establishment cannot provide assurance that tissue is being disposed of as soon as reasonably possible. Although the families consent for disposal or repatriation may have been obtained, the establishment have not undertaken regular audits of these samples to establish which samples should be disposed of. There is no documented procedure in place for following up with third parties to determine when the coroner's authority has ended. Tissue has been transferred to an external third party for storage annually without determining if the coroner's authority for retention has ended. During the inspection, cases were identified where tissue taken at PM examination had been retained: • A case from 2017 was not found on the laboratory information management system (LIMS). • A case from 2019 were a discrepancy in the number of blocks recorded on the tissue form is different to the information inputted into LIMS. • A case from 2021 were no tissue form had been scanned onto LIMS. • Two cases from 2022 and 2023 were it has been recorded that blocks and slides have been disposed but no date recorded on LIMS. At the time of the inspection no consent forms were found for six cases reviewed. Subsequently consent forms have been found for five of the cases. There is a risk that the establishment may be storing tissue against the wishes of the family.	**Cumulative critical**

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Audits have not been completed since the last inspection: a schedule of audits is now in place however, the scope for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient horizontal audits to check compliance with documented procedures, the completion of records and traceability of bodies or tissues. *As a result, standard GQ2 (b) cannot be met*	**Major**
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 establishment could not provide evidence that portering staff and out-of-hours general managers are trained for the activities they undertake.	**Major**
c) Staff are assessed as competent for the tasks they perform	Portering staff and out-of-hours general managers involved in licensed activities have no on-going competency assessments following initial training and sign-off. Competency assessments for staff working in the mortuary are not up to date. *This shortfall was identified at the previous inspection in 2021.*	**Major**
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	Portering staff, general managers and consent seeking staff are not aware of how to identify and report incidents that must be reported to the HTA.	**Major**
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	There are no risk assessments in place related to the licensed activities. *As a result, standard GQ6 (b) cannot be met.* The route staff transfer deceased to the external body store and funeral directors (FD) to the transport vehicle is on an uneven road surface and can be overseen by Trust staff and nearby contractors working. The external unit is accessed by a ramp however, the ramp to the door is steep and difficult to maneuver a trolley up. The alternative route used by portering staff to transfer deceased from ward to mortuary can be overseen by members of the public and Trust staff. This route has not been risk assessed. This does not ensure the dignity of the deceased and there is an increased risk to accidental damage to the deceased due to the uneven road surface and steep ramp.	**Major**
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Although staffing levels are currently on the establishment's risk register, there is a risk that staff will be unable to complete the current action plans in place for reviewing documents and training of staff by the expected deadlines.	**Major**
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	There is no documented procedure in place for transportation of the deceased from maternity wards to the laboratory. There is an increased risk of loss or disposal of a whole foetus or foetal tissue.	**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	Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: • Hair was found on the drains in the post mortem (PM) suite; • Dried blood spots were seen on the walls of the PM suite; • The floor of the PM room is heavily covered with limescale; • Areas of exposed plaster on the walls of the body store; • The FD entrance doors are wooden and are heavily chipped making it porous; • Deteriorating seals around the PM tables; • Floor in PM room deteriorating around the drains; and • The floor of the external storage unit was stained. The establishment should remove inappropriate equipment used for cleaning from the PM suite.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The door outside the FD entrance is left permanently open. This door is used to access pathology laboratories but has no lock or swipe card access. Although the mortuary door has swipe card access there is no audio/visual for staff to verify who is requesting access. The inspection team observed a FD arriving to collect a deceased who knocked on the hatch cover to the mortuary office; staff opened the mortuary door without verifying who was requesting access. This poses a risk to staff and of staff allowing unauthorised access to the mortuary. The door to the mortuary office areas is via the collection area outside the main pathology building. Although this is swipe card access this is a single glass paned office door and is not secure.	**Major**
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 no bariatric freezer storage to meet the needs of the establishment.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
b) Equipment is appropriate for the management of bariatric bodies	Equipment is not appropriate for the management of bariatric bodies.	**Major**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	L&D has been unable to provide the service records for the ventilation system and staff are not aware if the ventilation system is operating to the required standard. In addition, there is a gap between the PM suite wall and the former observation gallery glass partition. This gap will mean that the ventilation system may not be working efficiently and maintaining the required ten air changes an hour or negative pressure. This poses a potential health and safety risk to all staff. *See advice item 5.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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).	There is no confirmation of receipt of tissue or organs sent off site for analysis.	**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 hoists are suffering from signs of wear and tear; small areas of rust and peeling paint were seen making it difficult to clean and decontaminate sufficiently.	**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.	GQ5(a)	The DI is advised to place signage in the mortuary and maternity units to raise awareness amongst all staff working there of the importance of reporting any incidents, including a list of all the appropriate HTA Reportable Incident (HTARI) categories.
2.	T1(d)	The DI may wish to consider aligning the naming convention of the fridges the same as Bedford Hospital to mitigate the risk of the incorrect fridge location being inputted into the electronic system when staff work cross site.
3.	T1(h)	The DI is advised to label the shelves and have an inventory on the products of conception (POC) fridge so that staff are aware of those POCs that are for sensitive disposal and those for release to the family.
4.	PFE2(f)	The DI is advised to undertake trend analysis of the temperatures to identify trends and the extent of any variations in storage temperatures.
5.	PFE3(f)	While the majority of equipment does undergo regular maintenance, this is overseen by estates and mortuary staff had difficulty accessing the maintenance reports for the fridges, trolleys and ventilation during the inspection. The mortuary should have copies to provide assurances the equipment is functioning to the required standard. This would allow mortuary staff to identify when servicing, maintenance and equipment issues need to be escalated to senior staff.

Background

Luton and Dunstable Hospital (L&D) are licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

L&D has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in July 2021 which was a virtual regulatory assessment only.

Since the previous inspection, the establishment has introduced a CT scanning service.

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.

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 relating to licensed activities, cleaning records for the mortuary and post-mortem room, records servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room.

Audit of records

Audits were conducted for four bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic system. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from seven PM cases, including audits of the consent documentation for the retention of these tissues. Six discrepancies found (see shortfall against T2(a)).

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists (APT), quality lead, laboratory personnel, portering staff, pathologist and deputy mortuary manager.

Report sent to DI for factual accuracy: 12 April 2024

Report returned from DI: 20 May 2024

Final report issued: 1 August 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.