Inspection report on compliance with HTA licensing standards
Inspection date: **9 February 2023**

# Lister Hospital

HTA licensing number 12110

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 |
|---|---|---|---|
| **Lister Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **Accident and emergency department** | - | *Carried out* | - |
| **Histology department** | - | - | *Carried out* |
| **Maternity department** | - | - | - |

## 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 Lister Hospital ('the establishment') had met the majority of the HTA's standards, four major and two minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These relate to consent training and competency assessment of staff, SOP content and following up with the Coroner to determine families wishes. There are also shortfalls relating to capacity, contingency planning, arrangements to ensure the dignity of the deceased and alarm testing of temperature monitored storage units.

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 |
|---|---|---|
| **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. | The training package for consent seekers of perinatal PMs is not mandatory and as such the DI cannot assure themselves that consent is always sought from a trained individual. Furthermore, it was identified that there is a frequent occurrence of perinatal consent forms being completed incorrectly which results in staff having to re-consent bereaved families. | **Major (cumulative)** |
| d) Competency is assessed and maintained. | Staff competency in seeking consent for adult PM examination is not assessed.<br>Staff competency in seeking consent for perinatal PM examination is not mandatory. | |
| **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. | Some of the establishment's Standard Operating Procedures (SOPs) relating to mortuary activities lack sufficient detail.<br>These include, but are not limited to-<br>• The documented contingency plan does not cover the use of the overflow 'Surge' unit.<br>• Although alluded to, the documented contingency plan does not detail the names and contact numbers of Funeral Directors that provide contingency services.<br>• The documented contingency plan does not cover freezer contingency arrangements.<br>• The release of deceased SOP details the 3 points of identification checks that are carried out prior to release however this is not alluded to in other relevant SOPs such as the SOP for out of hours releases (MORTSOP26) or the SOP for release directly to the funeral directors (MORTSOP27).<br>• The SOP for the storage of bodies (MORTSOP17) provides important details of what to do if the patient is bariatric however it does not include considerations if the body is of a different shape or in a position which would prevent them for being admitted following standard procedures.<br>• There is a robust procedure for condition checking the deceased however this is not detailed in the establishment's SOPs, MORTSOP17 and MORTSOP25, which relate to storage arrangements and long-term storage arrangements. | **Major** |
| **T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's Codes of Practice** | | |
| b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary. | Due to the change of staffing, there is currently no procedure for following up with the Coroner to obtain the families wishes form for material taken at PM. This means that the establishment staff cannot assure themselves that tissue is not kept for longer than necessary.<br>During the site visit, the inspection team carried out an audit of tissue taken during PM. The establishment could not provide documented evidence that they had | **Major** |

| | | |
|---|---|---|
| | consent to retain the samples from 2020, 2021, 2022 and 2023 as the family wishes form had not been obtained from the Coroner. | |
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue** | | |
| a) Storage arrangements ensure the dignity of the deceased. | Although not in use during the inspection, the overflow body storage unit is directly in sight of the hospital's pedestrian access routes and car park. With the door open there is a risk that shrouded bodies on the racking are viewable.<br>This was identified at the inspection in February 2022.<br>*After highlighting the issue in a pre-inspection meeting corrective action was immediately taken and a canopy was in the process of being erected during the visit.*<br>There is a lockable door between the viewing room and the body store however, when closed, there is a large gap between the door and the floor (approximately 6 inches). As viewings take place within mortuary working hours it is highly likely that families will be able to hear what is going on in the body store. As well as not being respectful to the family, there is also a risk of patient confidentially being breached. | **Major** |

***Minor shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue** | | |
| b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity. | Contingency storage arrangements and temporary body storage facilities are being used by the establishment continually and have been for a number of years.<br>The units themselves are beginning to show signs of wear with the zips not fully sealing the units. Although temperature monitored and alarmed there is a risk that their efficiency will start to be compromised. | **Minor** |

| | | |
|---|---|---|
| e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range. | Whilst fridge and freezer units are alarmed, there is no formal testing of the fridge and freezer temperature alarms to ensure call-out procedures work and are followed. | **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 practices:

| Number | Standard | Advice |
|---|---|---|
| 1. | C1(b) | There is an SOP for the consent seeking process for hospital PMs entitled 'Consent process for an Adult, Children and Babies Post Mortem (MORTSOP15)'. Although named as covering children and babies the procedure contained within and the associated documents are reflective of the practices for adults only. The DI is advised to rename the SOP or extend it to the cover the children and baby consent seeking procedures. |
| 2. | C1(e) | The establishment gives the option to families for retention of PM material for future use including education, training and research. The establishment does not carry these out and has not done for many years. The DI is advised to consider providing this information to families to set expectations and to ensure that any consent given by families for tissue to be retained is suitably informed. |
| 3. | GQ1(g) | There is one member of trained staff that is responsible for the material in the pregnancy loss pathway. In the past there has been some backlogs in actioning the sensitive disposal. To ensure that material is not retained for longer than necessary the DI is advised to train more members of staff in the process. |
| 4. | PFE2(a)<br>PFE3(c) | The PM room has louvre-style windows that are opened in the summer when temperatures rise. Although risks have been considered, the DI is advised to fully document the risks including assessing how opening the windows during PM sessions may affect;<br>1) security, including whether there is a possibility of anyone seeing into the facility and;<br>2) how the open windows may affect air flow.<br>Air conditioning may need to be considered. |
| 5. | PFE3(c) | Despite a recent refurbishment the PM room ventilation report noted that the system was in a 'poor condition'. Although the air changes met the HTA's standard the DI is advised to monitor the system closely and carry out the recommended repairs to ensure that it continues to meet the requirements. |
| 6. | PFE3(f) | The annual servicing of equipment in the body store has been postponed due to the expiration of a maintenance contract. Rescheduling has been organised however the DI is advised to oversee this to ensure that it takes place as planned and that they are no further delays and cancellations. |

## Background

Lister Hospital has been licensed by the HTA since August 2007. This was the sixth inspection of the establishment; the most recent inspection took place in February 2022.

Since the previous inspection, there has been some significant changes to the licence arrangements including the change of Designated Individual (DI) in February 2022 and a change in Corporate Licence Holder contact (CLHc) in January 2022. The establishment have also had a refurbishment of the mortuary body store and PM room in July 2022.

## 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. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, ventilation, and equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs was also reviewed.

*Visual inspection*

The inspection team undertook a site visit inspection of the premises which included the mortuary body storage areas, the PM suite and the storage arrangements for relevant material held within the facility.

*Audit of records*

The inspection team undertook audits of traceability for five bodies in storage. This included community and hospital cases in the permanent fridges, temporary fridge units and a long-stay body in the freezer. Traceability details were cross-checked between the identification band on the body and information in the mortuaries electronic register. All bodies were fully traceable, and no discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for six cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. The establishment could not provide documented evidence that they had consent to retain the samples from 2020, 2021, 2022 and 2023 as the family wishes form had not been obtained from the Coroner.

*Meetings with establishment staff*
The assessment team met with staff carrying out activities under the licence, including the Mortuary Manager, an Anatomical Pathology Technologist (APT), a trainee APT, the Portering and Transport Manager, a Bereavement Assistant, a Bereavement Midwife, a Consultant Obstetrician, the Cell Pathology Manager and the General Manager for Diagnostics who holds the position of DI.

**Report sent to DI for factual accuracy:** 8 March 2023

**Report returned from DI:** No factual accuracy or request for redaction comments were made by the DI

**Final report issued:** 27 March 2023

## 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 October 2023

**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.