Site visit inspection report on compliance with HTA licensing standards
Inspection date: **25 – 26 February 2020**

# Leeds General Infirmary

HTA licensing number 12231

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**<br>**Leeds General infirmary** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **Maternity department** | - | *Carried out* | *Carried out* |
| **Accident & Emergency (A&E) department** | - | *Carried out* | - |
| **Neonatal Intensive Care** | - | *Carried Out* | - |
| **Paediatric Intensive Care** | - | *Carried Out* | - |
| **Old Medical School building** | - | - | *Carried out* |

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|---|---|---|---|
| **Satellite site**<br>**St James's University Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **Maternity department** | - | *Carried out* | *Carried out* |
| **A&E department** | - | *Carried out* | - |
| **Neonatal Intensive Care** | - | *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 Leeds General Infirmary (the establishment) had met the majority of the HTA's standards, five major and eight minor shortfalls were found against standards for Governance and Quality, 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**

***Major 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. | Some standard operating procedures (SOPs) describing the procedures for identification of the bodies do not provide sufficient details of identification procedures. These SOPs do not always make it clear that a minimum of three identifiers of the deceased should be checked, what the identifiers could be, what they should be checked against and at what stage of the procedure.<br>*Refer to shortfall against standard T1(c).* | **Major** |

| T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail | | |
|---|---|---|
| c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier | The establishment's procedures for identification of bodies do not ensure that a minimum of three identifiers of the deceased are used.<br>• Bodies admitted from the community may only be identified with one identifier (the name of the deceased).<br>• Bodies may be released from the mortuary using one identifier (the name of the deceased) to check the identification of the deceased. The procedure for release of bodies does not state that funeral directors should provide a minimum of three identifiers of the deceased to collect a body.<br>• The procedure for preparing adult and paediatric bodies for viewing states that only the name of the deceased is used to prepare the body from the details in the mortuary diary and viewing record form, respectively. The procedure for conducting viewings does not include steps to check a minimum of three identifiers of the deceased provided by relatives against the identification on the body before a viewing takes place.<br>• The procedure for adult viewings out of hours states that one identifier (the name of the deceased) is used to locate and prepare a body for viewing. The procedure for paediatric viewings out of hours is not documented.<br>• The procedure for trainee pathologists does not include the requirement to check a minimum of three identifiers of the deceased prior to starting the PM examination. | **Major** |

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| **PFE2 There are appropriate facilities for the storage of bodies and human tissue.** | | |
| a) Storage arrangements ensure the dignity of the deceased | The arrangements for storage of the collection of organs in the Old Medical School does not ensure the dignity of the deceased. The room has not been cleaned to an appropriate standard. There is a significant amount of dust and debris on the floor. | **Major** |
| c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs | The establishment does not have sufficient freezer storage capacity for long-term storage of bodies and does not have contingency arrangements for freezer storage. The inspection team found that some bodies had not been transferred to freezer storage in line with the establishment's procedure for long-term storage of bodies. | **Major** |
| **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 PM room ventilation system records for the hub site show that the gradient of air pressure in the PM room is positive. This poses a potential health and safety risk.<br>*The establishment provided verbal assurance that this was rectified on the day of the site visit inspection. The establishment provided documented evidence to demonstrate that the shortfall had been addressed prior to the report being finalised.* | **Major** |

***Minor Shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **GQ1 All aspects of the establishment's work are governed by documented policies and procedures** | | |
| e) There is a system for recording that staff have read and understood the latest versions of these documents | Not all staff have signed to confirm they have read and understood the procedures that govern their work. | **Minor** |
| **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 | Clinical Site Managers responsible for releasing bodies from both mortuaries out-of-hours have not been trained in the procedure since 2016. | **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 | The inspection team identified incidents in the establishment's incident log that should have been reported to the HTA. This includes some near miss incidents. | **Minor** |

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| **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). | The establishment do not receive confirmation that toxicology specimens sent off-site have arrived at the receiving laboratory. | **Minor** |
| **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 | At both sites, the walls, doors and doorframes in the body stores and PM rooms have areas of minor damage exposing the underlying porous material. Porous surfaces cannot be adequately cleaned or disinfected. | **Minor** |
| 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) | At both sites, the door between the viewing suite and the mortuary cannot be secured to prevent relatives from accessing the body store area.<br>At the satellite site, the service door between the PM room and body store was open. The door is also immediately adjacent to the staff room. This allows access to the PM room and, or observation of activity in the PM room from the body store. | **Minor** |
| **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 | Documented temperature records for the mortuary storage units at the hub site have not been completed consistently and it is not clear how often the electronic system records are reviewed. | **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 | There are items constructed of wood in the PM room at the satellite site. For example, there is a wooden desk with drawers and a wooden instrument handle. In addition, there is seating with material padding. These items cannot be adequately cleaned or disinfected.<br><br>In the PM room at the hub site, there are small areas of rust on the bases of the PM tables, meaning that these surfaces are porous. | **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 update the procedure for obtaining informed consent for hospital PM examination to be clear that under the HT Act a child is defined as being under 18 years old. |
| 2. | C1(g) | The DI may wish to consider including a space in section three of the adult consent form for PM examination to record the organs that relatives give consent to be retained during PM examination. The DI is advised to refer to the HTA's model consent form: www.hta.gov.uk/policies/post-mortem-model-consent-forms. |
| 3. | GQ1(a) | The DI is advised to implement a documented procedure for transfer of bodies from the remote body store areas at the satellite site to the main mortuary. |
| 4. | GQ1(d) | The DI is advised to ensure that the SOP for PM room cleaning and disinfection and the building and equipment checklist are regularly reviewed. |

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| 5. | GQ2(a) | The DI is advised to consider increasing the number of cases included in traceability audits of bodies and tissue. This will help provide assurance that traceability systems for bodies and tissues are robust. |
| 6. | GQ6(a) | The DI is advised to ensure that risk assessments relevant to SOPs are updated when procedures are reviewed. |
| 7. | T1(g) | The DI is advised to consider implementing checks of the number of tissue blocks received against the tissue block form upon arrival of the samples at the laboratory. This will help to strengthen the traceability systems for tissue taking at PM examination. |
| 8. | PFE1(a) | The DI is advised to remove surplus equipment and items from the PM room at the satellite site. This will help to make the area easier to clean and maintain. |
| 9. | PFE1(c) | The DI is advised to ensure that records of cleaning are consistently completed to demonstrate that cleaning tasks have been carried out. |

**Background**

Leeds General Infirmary has been licensed by the HTA since March 2008. This was the fourth site visit inspection of the establishment; the most recent previous inspection took place in November 2015.

Since the previous inspection, the viewing facilities at the hub site have been refurbished and an additional 30 refrigerated body storage spaces have been installed at the satellite site in a new storage facility remote from the main mortuary.

**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 covering the licensed areas at the hub and satellite site. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuaries and the PM rooms, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

*Visual inspection*

The inspection included a visual inspection of areas covered by the licence at the hub site and satellite site including the mortuary body stores, PM rooms, viewing rooms, the pathology laboratory at the satellite site, maternity departments, and the gynaecology ward at the satellite site. No licensed activity is being undertaken in the gynaecology ward at the satellite site.

The inspection included review of a collection of organs stored under the licence at the hub site. The samples were stored prior to implementation of the Human Tissue Act 2004 on 1 September 2006 and are therefore 'existing holdings'.

*Audit of records*

An audit of traceability of bodies was conducted for nine bodies, including one body in frozen storage. This included checking identifiers of the bodies, storage locations, mortuary register details, mortuary database details and associated documentation. One minor transcription error was found in the documented storage location for one body; this did not affect traceability of the body.

Audits were conducted of tissue removed during PM examination for six adult coroner's cases, one adult consented case and five paediatric/perinatal cases (two coroner's cases and three hospital consented cases). The audits included details of tissue type, number of tissue blocks and slides retained, review of consent forms, other associated documentation and electronic database records. No discrepancies were found.

*Meetings with establishment staff*

The inspection included interviews with the DI and staff carrying out processes under the licence at both sites, including Anatomical Pathology Technologists, the Mortuary Manager, porters, pathologists, a specialist nurse for PM consent and a paediatric consultant.

*Materials held for the police*

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process. At the time of the inspection, no tissue was being stored at the establishment under the authority of the police.

**Report sent to DI for factual accuracy: 17 July 2020**

**Report returned from DI: 17 August 2020**

**Final report issued: 28 September 2020**

## 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: 2 July 2021**

## 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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.