Inspection report on compliance with HTA licensing standards
Inspection date: **7 and 12 July 2023**

Leighton Hospital
HTA licensing number 12145

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 **Leighton Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Leighton Hospital ('the establishment') had met the majority of the HTA's standards, two major shortfalls and one minor shortfall were found against standards for Governance and quality systems and Traceability.

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
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	Not all procedures related to the licensed activities had been risk assessed. These included but were not limited to risks to bodies when being transferred to, and stored in, internal and external contingency storage units. This poses the risk of accidental damage to a body.	**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	Whilst family members attending the mortuary for a viewing are asked to provide three identifiers, these are different to the identifiers on the body of the deceased. This means viewings are undertaken using only two identifiers, posing the risk of viewing of the wrong body.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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 inspection team was not assured all staff involved in mortuary duties were appropriately trained. Maternity staff who undertake release from the ward have not received training on the completion of the mortuary register. This poses the risk of release of the wrong body and the loss of traceability.	**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)	To ensure staff can identify and recognise the information as procedural instructions. The DI should consider transferring the perinatal consent seeking SOP (Standard Operating Procedure) into the Trust format.
2.	C2(b)	The DI should consider adding the date perinatal consent seekers received a competency assessment to the list of trained consent seekers. This will provide additional assurance that those seeking consent have been assessed as competent.

3.	GQ1(h)	The DI should consider sharing the HTA governance meeting minutes with porters when there is an area of discussion relevant to their practice.
4.	GQ5(a)	Whilst incidents are reported and acted upon in a timely way, there are currently two incident reporting systems in operation across sites in the pathology network. The DI should review the current processes to ensure PDs receive notifications about incidents to maintain adherence with the HTA incident reporting requirement of five working days following discovery.
5.	GQ6(b)	The DI is advised to expedite the ongoing review of the establishment's risk assessments.
6.	PFE1(d)	To provide additional assurance security systems in place remain effective. The DI should consider changing the mortuary alarm access code on a regular basis
7.	PFE3(f)	The systems and equipment within the mortuary are subject to regular testing and servicing. However, records are not kept within the mortuary and are only available upon request. The DI is advised to request copies of all maintenance, servicing, and repair reports so that they are easily accessible to the Mortuary Supervisor for review and monitoring purposes.

Background

Leighton Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2018.

Since the previous inspection, the establishment has merged services with two other NHS Trusts to create a pathology network, mortuary staff work across establishments.

There has been a change to key personnel with the DI changing in 2022 and the Corporate Licence Holder contact (CLHc) changing in May 2023, with a single mortuary manager to oversee the licensed establishments within the pathology network supported by a deputy based at the establishment.

There are plans in place to provide additional security for the outside entrance to the mortuary and external body store with the addition of a lockable gate. Additionally, there are plans to refurbish and update the viewing suite and extend the availability of appointments for viewings.

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: The inspection included a visual assessment of the establishment including body storage areas, PM room and viewing room. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

Standards assessed against during inspection

68 of the 72 standards were assessed. Standards GQ2(c) and T2(a)(c)(d) are not applicable as the establishment does not store, return, or dispose of tissue removed as part of a PM examination.

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, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff, porters, and consent seekers.

Visual inspection

The inspection included a visual assessment of the establishment including the PM room, body storage areas, viewing rooms and outside temporary storage facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Audits were conducted, onsite, of six bodies from refrigerated storage and one from frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. There were no discrepancies identified.

Audits of traceability were conducted for tissue removed at PM examination. These were limited to audits of the documentation

relating to transfer of tissue offsite and confirmation of receipt from the receiving establishment. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Mortuary Manager, Deputy Mortuary Manager, Pathologist, Trainee APT, Mortuary Porter and Bereavement Midwife.

Report sent to DI for factual accuracy: 20/07/2023

Report returned from DI: 26/07/2023

Final report issued: 27/07/2023

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: 23 August 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.