Inspection report on compliance with HTA licensing standards
Inspection date: 11&12 October 2022

Queen Elizabeth Hospital Birmingham

HTA licensing number 12329

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 **Queen Elizabeth 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 Queen Elizabeth Hospital Birmingham ('the establishment') had met the majority of the HTA's standards, nine major and one minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to consent policy, standard operating procedures, risk assessments, audits, viewings and security.

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
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 documented policy which governs consent for post-mortem examination and the retention of tissue which reflects the requirements of the HT Act and the HTA's Codes of Practice.	**Major**
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 SOP for viewing of the deceased lacks sufficient detail. Key steps are included but these do not specify how three identifiers of the deceased are used in the preparation of a body for viewing and at the time of arrival of viisitors to ensure the correct body has been prepared for the correct visitors.	**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	Risk assessments of procedures related to licensable activities do not identify all of the associated risks. Scoops are in use for storage of bodies at the base of the fridge units, both in the internal and external body store areas. Hydraulic body trolleys in use do not lower enough in order to reach these spaces. This poses a risk of staff injury and to the dignity of the deceased. This is not risk assessed.	**Major**
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	As GQ6 (b) above, mitigation is not in place to address the risks of injury to staff and to the dignity of the deceased when using the base of the fridge units for the storage of bodies.	**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	Viewings are taking place using less than three identifiers of the deceased at the point of preparation of the body and at the time of arrival of visitors. This increases the risk of viewing of the wrong body. Furthermore, three identifiers of the deceased are not routinely used to identify wet tissue in storage in the laboratory awaiting transfer. This increases the risk of misidentification of tissue.	**Major**
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 inspection team conducted an audit of tissue in storage. One case was identified where tissue had been retained where disposal had been requested.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	Storage arrangements were not fully secure. A temporary body storage unit, which is situated in the funeral directors entrance bay is in an accessible area controlled by a roller shutter door which is not always closed when in use. The external components of the external fridge store are accessible on the outside of the unit. This leaves a risk of the external components being tampered with.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	There is swipe card access to the mortuary. The inspection team noted that multiple hospital employees had access to the viewing room waiting area which would then allow access to the body store in the event that the two doors, located between the waiting area and body store, were not manually locked. Furthermore, no audits have been conducted or other steps taken to limit access to the mortuary to those with a legitimate authorised purpose. The HTA is concerned to note that a minor shortfall was previously implemented in respect of this standard following the HTA inspection in 2017. The risk of unauthorised access was raised at that time.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst HTA matters are discussed, there are no minuted HTA meetings.	**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.	GQ5a	The DI is advised to add porters and nursing staff to HTARI training / SOP circulation.
2.	T1b	The DI is advised to audit the mortuary register to ensure funeral directors sign out.
3.	T2d	The DI is advised to record the method of disposal on tissue records rather than just the date of disposal on the laboratory spreadsheet.
4.	PFE1e	The DI is advised to consider visual methods to oversee activity in the viewing room and a visual notice to prohibit the use of cameras.

Background

Queen Elizabeth Hospital Birmingham, has been licensed by the HTA since 6 July 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in July 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
71 out of the total 72 HTA licensing standards were covered during the inspection (standards published 27 September 2022)". Standard T1(f) was not assessed as there is no long-term storage facility at this establishment.

Review of governance documentation
The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Evidence of staff training, and competency assessment were reviewed as well as the qualification certificates of mortuary staff. Traceability audits, risk assessments, meeting minutes, incidents, consent procedures relating to retained tissue were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, including the external body store, the viewing room, the PM room and the storage arrangements for relevant material held within the laboratory.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage. Traceability details were crosschecked between the identification band on the body, information in the mortuary register and associated patient tracking files. All were fully traceable.

Audits were conducted of tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, family wishes forms, and tissue blocks and slides being stored. Wet tissue in storage was also viewed. The inspection team noted that wet tissue was identified by being marked with only two identifiers. One case was found where tissue had been retained where disposal had been requested.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, portering staff, and the DI.

Report sent to DI for factual accuracy: 9/11/2022

Report returned from DI: 22/11/2022

Final report issued: 13/12/22

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 June 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.