Inspection report on compliance with HTA licensing standards
Inspection date: **18 September 2024**

Queen's Hospital
HTA licensing number 12154

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's Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-
Satellite site **King George Hospital**	Not Licensed	Licensed	Licensed
Mortuary (satellite site)	-	*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 Queen's Hospital ('the establishment') had met the majority of the HTA's standards, five major and five 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.

Major shortfalls

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 postmortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	Although there is training provided to consent seekers taking consent for adult and perinatal post mortems, doctors obtaining post mortem consent for early perinatal deaths are not trained in Human Tissue Act consent requirements.	**Major (cumulative)**
d) Competency is assessed and maintained	The establishment does not have a system in place for assessing staff as competent with the HTA requirements when seeking consent for perinatal post mortems.	

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) lack detail and do not reflect best practice guidance. These include, but are not limited to, SOPs detailing the process for: - HTARI reporting - Post mortem examinations - Obtaining consent to hospital post mortem examinations policy - Viewings - Specimen handling This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**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	Whilst staff know how to identify and report incidents, the inspection team identified two incidents which met the threshold for reporting to the HTA which had not been reported.	**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	Procedures for identification of bodies and tissue do not always use a minimum of three identifiers of the deceased. • Viewings of the deceased are arranged and accompanied by mortuary staff. For these viewings, no evidence was present to confirm they ask for a minimum of three identifiers of the deceased from relatives on arrival, or check a minimum of three identifiers of the deceased provided by relatives against the identification on the body before a viewing takes place. This poses the risk of the viewing of the wrong body.	**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)	Whilst there is CCTV covering the corridors to the mortuary, and the use of audio visual doorbells at all internal entrance points, there is no CCTV directly covering the main access doors used by porters and for the viewing suite. Furthermore, out of hours, there is no intruder alarm or internal CCTV oversight. This poses the risk of a serious security breach.	**Major**

Minor shortfalls

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 scheduled Pathology Governance Group meetings do take place, there are currently no documented meetings relating to HTA activity involving the Designated Individual, mortuary staff and staff working outside the mortuary who undertake activities under the licence.	**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	Although contracted Funeral Directors, who carry out mortuary activities out of hours, receive regular training from their trade association, they have not received relevant training based on HTA standards from the mortuary team.	**Minor**
c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured all staff who undertake mortuary duties receive regular competency assessments. • Contracted Funeral Directors are not assessed as competent for tasks undertaken under the licence. • At the time of the inspection the establishment had not submitted evidence to confirm mortuary staff involved in facilitating viewings are competency assessed in the viewing process.	**Minor**
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 is insufficient written guidance for staff to minimise the risk of a reportable incident. Whilst risks are assessed on a regular basis, the inspection team were not assured all potential HTA reportable incidents have been identified and risk assessed.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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, the alarms are not tested regularly to ensure that they trigger when temperatures go out of upper or lower set range. This includes testing of the alarms out of hours.	**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.	PFE1 d)	Whilst the mortuary is secure, an exterior door at King George Hospital, leading to the corridor of the internal entrance to the mortuary, is currently permanently propped open. This door should be repaired and secured to ensure only appropriate staff have access to this corridor.
2.	PFE2 a)	The internal porters entrance door at King George Hospital leads from the corridor directly into the body store, as such the mortuary have implemented the use of a foldable privacy screen to prevent oversight of the deceased from this corridor into the body store. During the onsite visit it was demonstrated that the current privacy screen is limited in its function due to its height. The DI is advised to reassess current measures to ensure they are fit for purpose.
3.	PFE1 d)	During a fire alarm the security locks on mortuary doors disengage and staff are deployed to ensure that security is maintained. The DI is advised to work with colleagues in the fire safety team at the establishment to ensure that the safest and most secure procedures are upheld in the event of an emergency.
4.	PFE1 a)	During the onsite visit the inspection team noted that the air handling unit in the viewing room at King George Hospital was excessively loud. This has the possibility to negatively impact a viewing and may also indicate failings with the unit itself. The DI is advised to investigate and rectify this issue.
5.	GQ5 d)	Although recent training has been provided, the inspection team reviewed records of a number of incidents occurring during last offices. The DI is advised to continue raising awareness at ward level regarding the dignity of deceased and what the mortuary expects of ward staff.

Background

Queen’s Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent

previous inspection took place in September 2022. Since the previous inspection, a licence amendment was granted for a satellite site at King George Hospital.

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 relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection

The inspection team undertook an unannounced visual inspection of the hub and satellite premises including the mortuary body storage areas, the post mortem room and the viewing suites. The inspection team also observed the process for release within the mortuary.

Audit of records

Audits were conducted for eight bodies from refrigerated storage across both sites. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified.

Meetings with establishment staff

The inspection team met with staff carrying out activities under the licence, including the Mortuary Manager, a senior APT, a Bereavement Midwife, a Porter and the Designated Individual.

Report sent to DI for factual accuracy: 4 November 2024

Report returned from DI: 19 November 2024

Final report issued: 21 November 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: 21 March 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.