Inspection report on compliance with HTA licensing standards
Inspection date: **02 August 2023**

Kingston Hospital

HTA licensing number 12023

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 **Kingston Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*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 Kingston Hospital ('the establishment') had met the majority of the HTA's standards, three major and five minor shortfalls were found against standards for consent training, document management, external mortuary security and premises maintence.

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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	There is no SOP in place for staff seeking consent for perinatal/paediatric post mortem (PM) examination.	**Major (Cumulative)**
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	At the time of the inspection, the establishment were unable to provide evidence of training for staff seeking consent for perinatal/paediatric post mortem examination. *This combined with shortfall C1(b) amounts to a cumulative major shortfall as it poses an increased risk of a breach of the consent codes of practice or the Human Tissue Act.* *As a result, standards C2 (b), (c) and (d) could not be assessed.*	**Major (Cumulative)**
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	The transfer of bodies from the wards involves leaving the main building to access the mortuary. This route includes the trolley passing over a cable protection cover due to ongoing construction work. This transfer procedure has not been risk assessed and poses a risk to accidental damage to bodies. *Since the inspection an incident has been reported to the HTA relating to the above risk.*	**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)	The mortuary is a standalone building on the hospital site. The inspection team identified two sides of this building, with windows and a fire exit, which were not covered by CCTV. In addition, benches and discarded cigarettes indicates that this area has recently been occupied. This poses a risk to security and unauthorised access to restricted areas.	**Major**

Minor 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.	The Histology SOP for retaining tissue does not provide a timeline for following up tissue taken at post mortem following the Coroner's jurisdiction finishing. Furthermore, the SOP incorrectly states that tissue is kept for 30 years if the Coroner is unable to ascertain a next of kin. The establishment therefore could appear to be storing tissue without appropriate consent under the Human Tissue Act. *This document was amended by the Designated Individual at the time of the inspection and the inspection team gained assurances that this practice was not followed and tissue was not retained without consent.*	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	There is a system to record that the latest version of documents have been sent to staff, however it does not record if they have been read, acknowledged or understood.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst there is a documented schedule of audits, this does not contain sufficient audits covering access to the mortuary and security arrangements.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

c) Staff are assessed as competent for the tasks they perform	Whilst training is in place, porters do not undergo competency assessments to ensure they have understood the training provided, and are competent to complete mortuary specific tasks.	**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	Although the mortuary premises are subject to regular cleaning, the age and subsequent deterioration of some areas means there is a risk that they cannot be cleaned or decontaminated effectively. Examples include: • minor areas of exposed plaster within the fridge room; • minor areas of exposed wood on door frames; and • perished seals to the base of the post mortem tables.	**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.	GQ1(c)	The DI and mortuary manager are advised to include condition checks of all perinatal and paediatric deaths admitted into the mortuary as part of the established condition check procedure used for adults.

2.	GQ1(h)	The DI is advised to continue the planned HTA meetings with all Persons Designated on the licence.
3.	GQ2(c)	Whilst regular, tissue audits are currently completed *ad hoc*. The DI is advised to include this in the mortuary audit schedule.
4.	PFE3(a)	The DI is advised to monitor the minor rust on the mortuary trolleys, and slightly perished seals on the fridge doors, as any further deterioration may result in a shortfall of standard PFE3(a).

Background

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

Since the previous inspection, there has been a change to the Designated Individual in January 2023, and an extension of bariatric fridge spaces.

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

69 of the 72 HTA licensing standards were covered during the inspection. Consent standards C2 (b), (c) and (d) could not be assessed due the absence of consent training records, and subsequent shortfall to C2(a).

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection
The inspection included a visual assessment of the mortuary fridge room, post mortem room, tissue storage areas and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage and one from frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from three coronial, and one hospital, consented case. These included audits of the consent documentation for the retention or disposal of these tissues. One minor discrepancy was identified, where the consent taker had selected more than one option for tissue retention. This was not sufficient to amount to a shortfall, but oral advice was given to the establishment at the time of the inspection.

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the DI, APT, Mortuary Porter, Pathologist, and Bereavement Midwife.

Report sent to DI for factual accuracy: 17 August 2023

Report returned from DI: 04 September 2023

Final report issued: 08 September 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: 22 January 2024

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.