Inspection report on compliance with HTA licensing standards
Inspection date: **15 & 17 November 2022**

George Eliot Hospital
HTA licensing number 12171

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 **George Eliot 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 George Eliot Hospital ('the establishment') had met the majority of the HTA's standards, two major and eight minor shortfalls were found against standards for Consent, Governance and quality systems, and Premises, facilities and

equipment. These related to competency assessment of some staff seeking consent, mortuary capacity, record keeping, mortuary staffing and maintenance of the rear of the premises.

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
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment have a temporary contingency body storage unit in operation to manage mortuary capacity. This is sited to the exterior of the mortuary. Internal storage capacity is currently on the Trust risk register as it has been identified as not sufficient long term to meet body storage requirements. The establishment have however, started identifying actions to address the risks associated with the lack of suitable permanent body storage capacity.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have frozen storage capacity for bariatric bodies requiring long term storage. Furthermore, the establishment identified that general freezer capacity is often not sufficient based on current needs to move bodies into long term storage. The establishment have however, started identifying actions to address the risks associated with the lack of freezer capacity.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Whilst all staff within the establishment seeking consent for post mortem examination are trained and regular refresher training is provided, some consent seekers have not had a recent assessment of competency in the consent seeking process.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The mortuary have many documented procedures in place to prevent practices which disregard the dignity of the deceased, however, at the time of the inspection the establishment had only recently implemented an electronic mortuary database with functionality to record condition and condition monitoring of bodies in storage. This now requires development of an associated condition monitoring procedure to ensure effectiveness.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The inspection team identified some omissions in information relating to receipt of bodies into the mortuary. This included but was not limited to, staff not signing to say who had completed identification checks or not recording the condition of bodies arriving from the community. Regular audits for accuracy and completeness of these records requires inclusion in the audit schedule.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	Whilst there is a system in place for the management of mortuary records, it does not include how long records should be retained for.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The inspection team identified a potential risk with the establishment's continual ability to deliver post mortem and mortuary services. The mortuary employs two staff who have occasionally undertaken lone working for extended periods due to an absence of the other staff member. Whilst locum staff have been made available at times to support the service, this risk requires review and incorporation into the Trust's organisational risk register to ensure there is sufficient resilience for mortuary staffing should both staff be unavailable to work at the same time and to reduce the possibility of staff lone working for extended periods.	**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	When internal mortuary capacity is insufficient, bodies are transferred a short distance to the contingency storage unit immediately to the rear of the mortuary premises. Whilst there has been some remedial work undertaken to the surface in the small mortuary yard body trolleys are required to cross to access the contingency unit, the surface is still uneven in areas. This increases the potential risk of accidental damage to the deceased during transfer.	**Minor**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst visitors attending the mortuary to view a body are always accompanied by a member of staff, the lock situated on the viewing room door to prevent access to the rest of the mortuary has not yet been replaced following a recent upgrade to the door. Furthermore, the viewing room does not have sufficient safety measures in place for staff to raise an alarm should this be required. Whilst the mortuary has a visitor access policy in place and conduct monthly access audits to ensure entry to the mortuary is restricted to those with a legitimate right of access, the visitor log in operation is not always routinely completed by those accessing the mortuary under the supervision of mortuary staff such as tissue retrieval teams.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
g) Bodies are shrouded or in body bags whilst in storage	The inspection team identified some bodies not fully shrouded whilst in storage. This can pose a risk to dignity of the deceased and potential accidental damage to bodies from coming into direct contact with internal components of the refrigerated unit.	**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 review the Care After Death Policy and the SOP in place for seeking consent for perinatal PM examination to ensure relevant information is reflective in each document.
2.	C1(g)	The DI is advised to remove the reference to the term 'Next of Kin (NOK)' from the form used to seek consent for adult PM examination. This is to ensure those seeking consent are consistently aware of the requirement for consent to be obtained under the HT Act from an appropriate person which may differ from a person identified as the NOK.
3.	C1(g)	The perinatal consent form in use refers to the HTA's old 'Code of Practice 3: Post Mortem Examination' (2009). The DI is advised to liaise with the referring establishment to ensure they are using the most recent version of the consent form.
4.	GQ1(a)	The mortuary manager is advised to review the suite of SOPs in place and combine relevant procedures into a singular step-by-step document. For example, there is an SOP for performing identification of a body prior to PM examination and SOPs for the actual PM examination. Combining documents such as this would reduce the number of SOPs requiring review and reduce the number of documents staff need to refer to when performing procedures making processes clearer.
5.	GQ1(a)	The mortuary has very recently implemented a dedicated traceability system for the management of bodies and material retained at PM examination. The mortuary manager is advised to review relevant SOPs as the system embeds to ensure they are reflective of practice.
6.	GQ4(a)	The DI is advised to review the following guidance: The retention and storage of pathological records and specimens (5th edition) Guidance from The Royal College of Pathologists and the Institute of Biomedical Science when addressing the associated shortfall with this standard.

7.	GQ1(g)	Whilst no licensable activity occurs in the maternity department and the bereavement midwives routinely attend the regular HTA meetings, the DI is advised to consider appointing a Person Designated in this area to oversee relevant procedures and consent seeking training and competency assessment requirements.
8.	GQ4(b)	Whilst there is a process in place for the management of errors in written records and staff are aware of how to rectify errors to ensure mortuary records are auditable, the DI is advised to review the mortuary record management SOP to ensure there is sufficient information on the correction of errors so any temporary locum staff can also be aware of expectations.
9.	GQ6(a)	The DI is advised to risk assess the risk of removal of relevant material without appropriate consent in the event of a needlestick injury to staff working in the PM room. This could be detailed in the PM examination risk assessment.
10.	T2(c)	The DI is advised to liaise with the Coroner service in regard to the family wishes forms in use. The form currently only details the name of the deceased which may cause a risk to the management of tissue and organs in the mortuary if there are several cases with a same or similar name. Furthermore, the forms do not contain sufficient information of the person giving consent to the retention or disposal of material retained at PM in order for the mortuary to establish that appropriate consent for retention is in place. It is further advisable for the forms to detail that material will be disposed of if the establishment are unable to use the material for the scheduled purposes listed on the form. This would assist those giving consent to make an informed decision regarding fate of the material.
11.	PFE2(e)	The DI is advised to review the upper alarm trigger point for the refrigerated units which is currently set at 10 degrees Celsius. This may pose a risk to bodies being stored at suboptimal temperatures for prolonged periods of time prior to the alarm sounding.
12.	PFE2(g)	The DI is advised to review with mortuary staff the updated HTA guidance for the shrouding of bodies on page 22 of the Code of Practice B – Standards and Guidance document to ensure compliance with HTA expectations in this area.

Background

George Eliot Hospital has been licensed by the HTA since October 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2017.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current Corporate Licence Holder contact (CLHc) was approved in August 2022, the current DI was approved in October 2022.

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 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 were reviewed. This included cleaning records for the mortuary and post-mortem room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, security audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, PM room and viewing room as well as the contingency storage unit in operation just external to the mortuary.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar name and a body stored longer term. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register, associated paperwork, and the electronic mortuary database. Whilst no discrepancies with traceability were identified, the inspection team noted that some mortuary paper-based records were not completed as required with relevant information for the receipt of bodies.

Audits were conducted of tissue taken at PM examination for the four cases in total the establishment are storing. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, and the tissue blocks and slides being stored. No discrepancies were identified.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff during the onsite visual inspection, a portering staff member, staff involved in the consent seeking process for both adult and perinatal PM examination, and the DI and mortuary manager during the virtual regulatory assessment.

Report sent to DI for factual accuracy: 06 December 2022

Report returned from DI: 19 December 2022

Final report issued: 29 December 2022

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: 30 May 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.