Inspection report on compliance with HTA licensing standards
Inspection date: **16 & 23 February 2023**

St Mary's Hospital
HTA licensing number 12357

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 **St Mary's Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	-

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 St Mary's Hospital ('the establishment') had met the majority of the HTA's standards, five major and three minor shortfalls were found against standards for Consent, Governance and quality systems and Premises, facilities and equipment. These related to consent policy, standard operating procedures, and dignity.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	There is currently no competency assessment in place for consent seeking.	**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 relating to body storage does not reflect HTA guidance in relation to long term storage. This presents a risk of accidental damage to bodies.	**Major**

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The inspection team noted one body in storage for over 30 days, requiring long term storage, had not been placed into the freezer. This body showed signs of decomposition.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is currently no recorded audit of bodies in storage to monitor length of stay and condition.	**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	There have been no reported incidents to the HTA since the last inspection. A review of the incident list revealed three incidents that had not been reported to HTA. These have subsequently been reported. The site inspection revealed one body in a state of early decomposition that had not been reported to HTA. This has now been reported. Despite a recently updated HTARI SOP, portering staff were not fully aware of what incidents should be reported to HTA.	**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 discussions take place on an informal basis, there are no scheduled, formalised, meetings involving the DI, PDs and staff working under the license.	**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	The inspection team noted damage to some walls in the body store revealing unsealed plaster. A section of wall skirting covering is missing revealing exposed plaster. This presents a risk of ineffective cleaning and decontamination.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	The body store was clean at the time of the inspection. However, there is currently no recorded cleaning schedule for the body store.	**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.	GQ2(a) & PFE1(e)	The DI is advised to add an audit of swipe card use to the audit schedule to strengthen security arrangements.
2.	GQ5(d)	Whilst incidents are discussed, the DI is advised to include this in regular documented HTA meetings with staff.
3.	T1(c)	The SOP and forms relating to viewings have recently been updated. The DI is advised to ensure that all staff are fully aware of the identification check process.

Background

St Mary's Hospital has been licensed by the HTA since 21 November 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in August 2018.

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 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 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. No discrepancies were noted. During this process, one body was found to show signs of decomposition.

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. No discrepancies were noted.

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

Report sent to DI for factual accuracy: 9 March 2023

Report returned from DI: 14 March 2023

Final report issued: 15 March 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: 9 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.