



St Marys Hospital
 HTA licensing number 12553

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 Marys Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Satellite site Hammersmith Hospital	Not licensed	Not licensed	Licensed
Mortuary (satellite site)	-	-	<i>Carried out</i>
Satellite site	Not licensed	Not licensed	Licensed

Charing Cross Hospital			
Mortuary (satellite site)	-	-	<i>Carried out</i>
Pathology lab	-	-	<i>Carried out</i>

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 Marys Hospital ('the establishment') had met the majority of the HTA's standards, nine major and three 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.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
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GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
<p>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.</p>	<p>SOPs do not cover all relevant procedures across the three sites. For example:</p> <p>For viewings, there are a number of separate SOPs relating to in hours and out of hours viewings. They do not cover a final check of three identifiers taken from or confirmed with relatives checked against the wrist band as a final check. The current procedure presents a risk of viewing of the wrong body.</p> <p>The HTA Reportable incident (HTARI) SOP does not fully cover all HTARI categories. The link to the HTA web site doesn't work.</p> <p>Please see advice for DI below.</p>	<p>Major</p>

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 do not cover all HTA risk areas across the three sites. Some appear to be written from pathology perspective rather than relating to mortuary procedures. One example relates to HTA reportable incidents and states that none have been reported and as such systems are robust. This is not accurate.

Risk assessments don't cover use of trays in lower levels of storage in the outside storage unit at St Mary's. The movement of trolleys across the step up into the unit is not risk assessed. .

At Hammersmith, the funeral service entrance is in a busy shared space used for laundry and delivery drivers access. The movement of patients through this area has not been risk assessed.

Major

<p>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</p>	<p>Current risk assessments, do not cover all HTA licensable activities across the three sites. Some appear to be written from a pathology perspective rather than relating to mortuary procedures.</p> <p>For example the risk assessment for HTA reportable incidents and states that none have been reported and as such systems are robust. This is not the case.</p> <p>Risk assessments don't cover the use of trays in the lower levels of storage utilised in the outside storage unit at St Mary's. This presents a risk of accidental damage and injury to staff. Also the step up into the unit with trolleys is not currently included in a risk assessment.</p> <p>At Hammersmith</p> <p>When the electricity fails, the doors to the mortuary close and lock, whilst staff can get out, no one can get in. This is not currently risk assessed. This poses a risk to the closure of a service.</p>	<p>Major</p>
<p>c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register</p>	<p>Low staffing levels and the subsequent risk to provision of service is not currently incorporated to the trusts risk register.</p>	<p>Major</p>

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)

The written mortuary register at St Mary's contains some illegible entries whilst this is not relied upon, it could cause a risk to release of the wrong body if supporting staff refer to it when completing out of hours releases.

Major

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.

<p>a) The premises are clean and well maintained</p>	<p>St Mary's</p> <p>The floor drains in the post mortem room had visible debris and had not been fully decontaminated.</p> <p>The drainage area close to the doors of the external body storage unit was blocked and required decontaminating.</p> <p>The drain plug hole for one post mortem tables had debris and required cleaning.</p> <p>Charring Cross</p> <p>In the body store there is damage to some of the walls with exposed plaster work which cannot be fully cleaned. The doors to the body store are damaged with exposed woodwork that cannot be fully decontaminated</p> <p>Hammersmith</p> <p>There is a long term leak from the Plant room above which means water is leaking into the mortuary office and the area where families wait to complete viewings.</p>	<p>Major</p>
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PFE2 There are appropriate facilities for the storage of bodies and human tissue.

<p>a) Storage arrangements ensure the dignity of the deceased</p>	<p>The air conditioning system in the post mortem room at St Mary's is unsuitable and inadequate to regulate room temperature. This means it is very cold during the winter months and very hot in the summer. This causes a risk of accidental damage to bodies by staff working with cold hands in the winter and the accelerated deterioration of patients in the summer.</p> <p>The viewing room at St Mary's has a stained glass window which is translucent in some sections. This presents a risk of members of the public being able to look through into viewing room area, where bodies are presented for families.</p> <p>At Hammersmith – The funeral directors entrance, at the bottom of the lift is a door to a busy public corridor. This means members of the public may have oversight of body transfers through the glass panels on these doors.</p>	<p>Major</p>
<p>d) Fridge and freezer units are in good working condition and well maintained</p>	<p>The floor of some fridges at St Mary's and Charring Cross cannot be cleaned thoroughly due to being constructed of metal sheeting with raised chequered patterning</p>	<p>Major</p>

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	<p>St Mary's In the post mortem room, an older hand pumped trolley and some other equipment including low steps had surface rust and cannot be fully decontaminated.</p> <p>Charring Cross The concealment trolley is defective, side guards and height adjustment don't always work. This poses a risk of accidental damage to bodies during transfer.</p>	Major

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Whilst full training is provided and recorded, there is currently no competency assessment in place for adult post mortem examination.	Minor

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

e) There is a system for recording that staff have read and understood the latest versions of these documents	The current system for document distribution is a manually operated shared document system. This does not alert the author or reader of review dates or changes to documents or procedures that require staff attention. This presents a risk of staff not being up to date with updates or changes to procedure.	Minor
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PFE2 There are appropriate facilities for the storage of bodies and human tissue.

f) Temperatures of fridges and freezers are monitored on a regular basis	Fridge and freezer temperature trends are being monitored at the St Mary's Hospital site but not currently monitored at the satellite sites.	Minor
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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.	GQ1a	The DI is advised to develop SOPs to cover mortuary procedures in all areas of HTA licensable activity. Limited staff are currently working across the hub and both satellite sites. This would establish clear guidance bespoke to all premises and activities governed by the trust.
2.	GQ6b	At Hammersmith, the viewing procedures utilises the use of a single door by the family affairs team as use of other doors can lead to vision into areas of body store. The DI is advised to add this procedure to risk assessments.
3.	GQ6c	The DI is advised to assess staffing levels in comparison to similar sized establishments, as part of their staff risk assessment and contingency plans.
4.	PFE1c	The DI is advised to update cleaning schedules to contain more detail of individual tasks that need to be completed.
5.	PFE1d	<p>At St Mary's, the external contingency body store is contained within a locked compound with high fencing. The DI is advised to secure the access to the refrigeration controls within the compound. This would prevent tampering should exterior security be breached.</p> <p>The DI is advised to add a review of swipe card use and CCTV checks to formal audits.</p>
6.	PFE1e	For out of hours access the Key to Mortuary at Charring Cross is held at security office. There is a clear process in place to book out this key and return it securely after use. Porting staff indicated that this procedure is not always followed and the key has, in the past, been obtained from an insecure unstaffed office. The process was reviewed on site with the reception and security team and appears to be robust if followed. The DI is advised to ensure that all relevant staff are fully aware of and compliant with the process.

Background

St Mary's Hospital has been licensed by the HTA since 15 February 2010. This was the fourth inspection of the establishment; the most recent inspection took place in June 2018.

Since the previous inspection, there has been some significant changes to the licence arrangements including the revocation of licensing for a satellite site at Samaritan Hospital for Women and a change of Designated Individual (DI) in 2020.

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 standard operating procedures, risk assessments, audits, incidents, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas, the PM suite at St Mary's as well as the storage arrangements for relevant material held at Charring Cross Hospital.

Audit of records

The inspection team undertook audits of traceability for eleven bodies in storage. This included community and hospital cases. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and

electronic records. No discrepancies were identified. It was noted that there were some entries in the mortuary register at St Mary's that were illegible.

Audits were conducted of stored tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified. One record required updating as result of further work in the laboratory where the production of additional slides had not been fully updated to the record. This was corrected instantly by staff.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including the DI who is the Mortuary Manager, an Anatomical Pathology Technologist (APT), a porter and staff involved in the consent seeking processes.

Report sent to DI for factual accuracy: 6 June 2023

Report returned from DI: 20 June 2023

Final report issued: 20 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.