

Walsall Manor Hospital
 HTA licensing number 12102

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 Walsall Manor Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Maternity	-	-	<i>Carried out</i>
Satellite site New Cross Hospital	Not licensed	Not licensed	Licensed
Mortuary (satellite site)	-	-	<i>Carried out</i>
Maternity	-	-	<i>Carried out</i>

Pathology lab	-	-	<i>Carried out</i>
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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 Walsall Manor Hospital ('the establishment') had met the majority of the HTA's standards, six major and one 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

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	At Walsall Manor Hospital, post mortem tissue in blocks and slides held in storage since 2004 for medical research is not subject to regular audits.	Major

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	Site managers at New Cross Hospital are not formally trained in out of hours procedures such as release of the deceased. This poses a risk of releasing the wrong body.	Major
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T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

a) Bodies are tagged/labelled upon arrival at the mortuary	The inspection team identified a trend, over the last six months, of bodies being received into the mortuary with missing identification bands. Whilst the mortuary team have robust systems in place to fully identify all bodies on arrival this creates a risk of misidentification.	Major
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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>At Walsall Manor Hospital</p> <p>The external fridge storage units are leaking, allowing moisture to enter in the area where the walls meet the roof sections and causing fluid stains to the interior. This presents a risk of accidental damage to bodies.</p> <p>The door to external fridge unit two is jarring against the floor surface and cannot be fully opened.</p> <p>In the post mortem room, sealant around sink units and where flooring uprisers meet walls is failing and cannot be fully decontaminated. The entrance doors are damaged at the bottom and show exposed wood that is porous and cannot be fully decontaminated.</p>	<p>Major</p>
<p>e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access</p>	<p>At Walsall Manor Hospital the viewing rooms are not fitted with panic alarms. This creates a risk to staff if they need to call for assistance in this area.</p>	<p>Major</p>

<p>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</p>		
<p>a) Items of equipment in the mortuary are in good condition and appropriate for use</p>	<p>At Walsall Manor Hospital, the trolleys in use in the external storage units are rusty and cannot be fully decontaminated.</p>	<p>Major</p>

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 training is up to date, there is currently no competency assessment in place for paediatric consent seeking across both the hub and satellite sites.	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.	PFE1d	<p>The Funeral director's entrance door at Walsall Manor Hospital has to be manually closed by staff. The DI is advised to consider the use of an automatic close device.</p> <p>At Walsall Manor Hospital, external store units are within locked fenced compounds. The DI is advised</p>

		to secure the access to the fridge and freezer controls within compound two. This would prevent tampering should exterior security be breached.
2.	PFE1e	At the Hub site, a swipe card use audit currently takes place every six months. The DI is advised to adjust the schedule to mirror the CCTV footage retention period. At the satellite site there is currently no swipe card use audit in place. The DI is advised to introduce an audit. This would strengthen security oversight.
3.	GQ1c	The DI is advised to review communication with the coroner relating to bodies arriving in a state of decomposition to reduce the risk of accidental damage to bodies.
4.	T1b	At Walsall Manor Hospital, multiple hand written records are completed relating to bodies in storage this creates a risk of errors. Whilst only one minor error was noted the DI is advised to review recording systems and consider reducing the amount of paper records to reduce the risk of errors.
5.	T1g	Whilst all tissue reviewed was fully traceable, the DI is advised to review submission processes to the laboratory at New Cross and consider utilising a unified system and paperwork to ensure effective traceability when processing material from multiple service users.

Background

Walsall Manor Hospital has been licensed by the HTA since 18 August 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2018.

Since the previous inspection, there has been a change to the Designated Individual and Corporate Licence Holder Contact.

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. The team also undertook a review of records relating to equipment servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units and mortuary, reported incidents, and staff training. Consent seeking procedures and information for relatives giving consent 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, PM room and viewing rooms as well as the area for storage of relevant material held within the laboratory. Maternity departments were also visited.

Audit of records

The inspection team undertook audits of traceability for nine bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the digital mortuary register and paperwork. One minor discrepancy was noted which was immediately corrected by staff.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent for PM examination forms (where relevant), the laboratory database, and 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, staff involved in the consent seeking process, staff from the maternity departments, the laboratory manager and the DI.

Report sent to DI for factual accuracy: 4 August 2023

Report returned from DI: 17 August 2023

Final report issued: 23 August 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: 14 November 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.